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No. 04 476 SEP 30 2004

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In The
Supreme Court of the United States

UNIVERSITY OF ROCHESTER,

Petitioner,

v.

G.D. SEARLE & CO., INC., MONSANTO CO., PHARMACIA CORPORATION, AND PFIZER, INC.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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September 30, 2004

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QUESTION PRESENTED

Section 112 of Title 35 of the United States Code provides, in relevant part, that a patent specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." The question presented is:

Whether the quoted language of § 112 imposes a second written description requirement, as some panels of the Federal Circuit have found, that is separate from and more demanding than the requirement that the written description enable any person skilled in the art to make and use the invention, whereas other judges of the court expressly have concluded that a separate written description requirement is unsupported by the statutory text and should be rejected.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner University of Rochester does not have any parent corporation and no publicly held company owns 10% or more of Petitioner.

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OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-30a) is reported at 358 F.3d 916. The order denying rehearing *en banc*, three opinions dissenting from the denial of rehearing *en banc*, and two opinions concurring in the denial of rehearing *en banc* (App., *infra*, 69a-122a) are reported at 375 F.3d 1303. The opinion of the district court (App., *infra*, 31a-68a) is reported at 249 F. Supp. 2d 216.

JURISDICTION

The court of appeals entered its judgment on February 13, 2004. A petition for rehearing *en banc* was denied on July 2, 2004. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 112 of Title 35 of the United States Code sets forth the information that must be contained within the specification of an issued United States patent. Section 112 provides, in relevant part:

§ 112 Specification

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
>
> * * *

INTRODUCTION

The Federal Circuit is deeply divided over whether 35 U.S.C. § 112 contains a written description requirement for a patent that is separate from and more demanding than the requirement that the patent specification include a "written description" of the invention sufficient "to enable any person skilled in the art . . . to make and use" the invention. In the instant case, a panel of the Federal Circuit held that § 112 contains such a separate written description requirement. The court of appeals denied rehearing *en banc* by a vote of 7 to 5, with several vigorous dissenting opinions on the issue. Indeed, the dissenters include one member of the court who agreed that such a separate written description requirement exists, but who nonetheless urged the court to hear the case *en banc* to resolve the "burgeoning conflicts in pronouncements" of the court on the issue. App., *infra*, 71a.

The decision below represents a fundamental shift in patent law arising from the court of appeals' creation of a separate written description requirement that is at odds with the longstanding statutory language, carefully chosen by Congress. The text of § 112 is straightforward, requiring only a written description of an invention sufficient "to enable any person skilled in the art . . . to make and use the same," *i.e.*, the enablement requirement.

In the decision below, however, the Federal Circuit insisted that the written description required by the first paragraph of § 112 must do more than enable skilled persons to make and use the invention – indeed, the decision below addressed written description but explicitly did not reach enablement. The decision went beyond an enablement standard by adopting, in a separate written description requirement, a new rigid standard that invalidates a patent if the specification does not describe every detail of the specific structure of the claimed invention, including, in the instant case, the identification of the exact chemical formula of a compound for implementing the patented methods of treatment. Through this new

requirement, a court may invalidate a patent regardless of the ability of a person of skill in the art to make and use the invention based on the written description provided in the patent. By doing so, the decision dispenses with the need to consider the perspective of, and to rely on evidence from, persons skilled in the art. Instead, the decision allows judges to decide that a patent is invalid on summary judgment, even when there has been no evidence introduced suggesting that skilled artisans would be unable to make and use the invention based on the patent's written description. The decision thus vitiates the statutory presumption of validity that attaches to a patent pursuant to 35 U.S.C. § 282.

Because the Federal Circuit's decisions ignore the statutory language linking a patent's written description to enablement, this separate written description requirement alters the balance between protection of basic research and protection of commercial products. In so doing, it undermines the Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212, which uses the patent system to effectuate the transfer of early-stage technology from research institutions to industry.

In an *amicus* brief filed in the Federal Circuit in 2002, the United States urged that court to address *en banc* the written description requirement of § 112, observing that the numerous decisions by the Federal Circuit that have addressed the issue have not provided clear or uniform guidance as to the meaning of the requirement.

Review by this Court is necessary to resolve the disagreement among the judges of the Federal Circuit (noted by more than fifty academic commentators, App., *infra*, 93a-117a), and to put an end to the misinterpretation of § 112. As explained below in one of the opinions dissenting from denial of rehearing *en banc*, "[t]he issue of whether patent law contains a separate written description requirement has percolated through various panels" of the Federal Circuit "on a variety of facts" and is now ripe for further review to resolve the differences of opinion that have developed. App., *infra*, 73a.

STATEMENT OF THE CASE

1. Statutory framework

a. Congress has exercised its constitutional authority to "promote the Progress of Science and useful Arts" under Art. I, § 8, cl. 8, through the establishment of a federal system for the issuance of patents, 35 U.S.C. §§ 1-13, which "offer[s] inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (citation omitted). Congress has identified the types of inventions that are "patentable" in 35 U.S.C. § 101 to include "any new and useful process, machine, manufacture, or composition of matter. . . ."

b. A patent is presumed valid under 35 U.S.C. § 282, and the "burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.* Invalidity of a patent can be established, *inter alia*, "for failure to comply with any requirement of section[]112. . . ." 35 U.S.C. § 282(3).

Section 112 sets forth the required contents of the specification that must be "annexed to the patent and be a part of such patent." 35 U.S.C. § 154(a)(4). Section 112 provides in its first paragraph that the specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1.

Section 112 provides in its second paragraph that the specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. The remaining paragraphs of § 112 detail the requirements of how the claims are to be set forth. The best mode provision of the first paragraph

and the claims provision of the second paragraph are not at issue in this case.

c. Congress has provided that appeals involving federally issued patents be heard by the United States Court of Appeals for the Federal Circuit. 28 U.S.C. § 1295. Because of that exclusive jurisdiction, there is no opportunity for other Circuits to interpret the language of the Patent Act and, thus, no possibility of an inter-circuit conflict on the matter of statutory construction at issue here, no matter how wrong the Federal Circuit's interpretation of the statute may be using general principles of statutory construction.

2. Factual background

a. Petitioner, the University of Rochester, is one of the nation's leading research universities. In 1990, Petitioner's team of scientists led by Dr. Donald Young discovered novel methods of treating pain, inflammation and other diseases in humans. These methods all involve selective inhibition of an enzyme known as cyclooxygenase-2 ("Cox-2").

Cyclooxygenases are enzymes that bring about the production of prostaglandin hormones in the human body. Prostaglandins perform certain housekeeping functions such as protecting the stomach lining. App., *infra*, 2a-3a. Prostaglandins can also cause pain and inflammation, however, when produced at the site of an injury or disease.

For many years, scientists thought that in humans there was only one cyclooxygenase – now known as Cox-1 – and that Cox-1 was responsible for the production of all prostaglandins, including those that cause pain and inflammation. Accordingly, drugs used to treat pain and inflammation – so-called non-steroidal anti-inflammatory drugs ("NSAIDs")[1] – were designed to inhibit the activity

[1] Examples of traditional NSAIDs include aspirin, ibuprofen, and naproxen. App., *infra*, 2a.

of Cox-1. Such NSAIDs thus inhibited Cox-1's production of the protective prostaglandins in the stomach, causing significant adverse side effects such as ulcers and bleeding. *See* App., *infra*, 2a-3a.

Dr. Young and his team made the remarkable discovery that there is a second cyclooxygenase enzyme in humans – now known as Cox-2 – that is the product of a distinct gene. They discovered that it is Cox-2 – not the previously known Cox-1 – that is responsible for causing inflammation, and that traditional NSAIDs worked because in addition to inhibiting Cox-1 they also inhibited Cox-2. App., *infra*, 3a. Petitioner's scientists realized that a new, better, and safer way of treating pain and inflammation was to selectively inhibit Cox-2 much more than Cox-1. In that way, pain and inflammation could be treated without inhibiting the production of prostaglandins that protect the stomach. App., *infra*, 3a; *see also* Fed. Cir. J. App. A87-147.

Petitioner's work in this area was pioneering. Respondents' chief medicinal chemist described the discovery of Cox-2 and its link to inflammation as the "holy grail in this area. . . ." Fed. Cir. J. App. A760.

The inventors published their groundbreaking discoveries in widely disseminated scientific journals, and discussed their findings at regional and international conferences. Fed. Cir. J. App. A87-89.

b. The research leading to the invention was funded by the National Institutes of Health. U.S. Patent 6,048,850 ("the '850 patent") at col. 1, lines 18-21 (Fed. Cir. J. App. A112). Thus, under the Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212, Petitioner is afforded the intellectual property rights and the right to file for a patent on, *inter alia*, the methods of treatment the University scientists invented based on their research. Petitioner therefore filed an application for a patent in September 1992, App., *infra*, 3a-4a, and the sufficiency of the specification in that application was not before the Federal Circuit. In June, 1995, Petitioner filed a continuation application which was

issued by the United States Patent and Trademark Office on April 11, 2000 as the '850 patent. *Id.* at 4a.

The '850 patent identifies Cox-2 as a novel pharmaceutical target for treating pain and inflammation. The '850 patent sets forth experiments that demonstrate that NSAIDs inhibit Cox-2, and that different NSAIDs inhibit Cox-2 to different degrees. The '850 patent does not set forth the precise chemical structure of a selective Cox-2 inhibitor. It does, however, describe suitable compounds by their characteristics, function and behavior in tests. It also describes materials and tests that enable scientists using routine skill to identify compounds that will selectively inhibit Cox-2 over Cox-1.

The disclosure of Cox-2 set off a race to identify compounds that selectively inhibit Cox-2. It took two major pharmaceutical companies – Pfizer and Merck – only a few months to identify selective inhibitors of Cox-2, and both companies filed patent applications directed to broad classes of compounds. Fed. Cir. J. App. A1278, A3082-3102.

3. Procedural background

a. District court. Petitioner filed suit in the United States District Court for the Western District of New York on the day its '850 patent issued, alleging that respondent Pfizer's sales of its selective Cox-2 inhibitors, Celebrex® and, later, Bextra®, infringed the '850 patent. App., *infra*, 5a. Petitioner sought injunctive and monetary relief. *Id.* at 6a.[2]

In May 2002, Respondents moved for summary judgment on the ground that the '850 patent is invalid under § 112, ¶ 1, for failure to meet the Federal Circuit's

[2] The other Respondents are predecessor entities to Pfizer. *See* App., *infra*, 5a n.2 (detailing corporate transformations of predecessors).

separate "written description requirement", because the patent does not disclose the exact chemical formula of a compound that selectively inhibits Cox-2 over Cox-1. Respondents contended that the patent's written description "must include a description of the structure or formula of the compounds that actually perform" the function of selectively inhibiting Cox-2. Fed. Cir. J. App. A163. In November of 2002, Respondents additionally moved for summary judgment on the ground that the '850 patent is invalid because its written description does not enable persons skilled in the art to practice the claimed methods of treatment – *i.e.*, lack of enablement. App., *infra*, 35a.

Petitioner opposed both of Respondents' motions and also filed a cross motion for summary judgment on the Federal Circuit's separate written description requirement. In addition to relying on the statutory presumption of validity under 35 U.S.C. § 282, Petitioner submitted the declarations of five experts in the field who explained that the '850 patent's written description enables persons skilled in the art to make and use the claimed methods of treatment without undue experimentation. Fed. Cir. J. App. A342-404, A1199-1412. Petitioner also submitted hundreds of pages of other documentary evidence demonstrating that persons skilled in the art can make and use the claimed inventions. *Id.*, A1413-3894. Respondents submitted no relevant evidence other than the patent itself in support of either of their summary judgment motions.

The district court granted Respondents summary judgment on both their motions. App., *infra*, 31a-68a. With respect to the Federal Circuit's separate written description requirement, the district court held that the '850 patent does not meet the requirement "as a matter of law," because "it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention." App., *infra*, 44a. The district court premised its ruling on the fact that the patent did not contain the exact chemical formula of a

compound that selectively inhibits Cox-2. App., *infra*, 44a-47a.

The district court also granted Respondents' motion on enablement, denied Petitioner's cross-motion, and dismissed the complaint. App., *infra*, 7a.

b. Court of appeals' panel opinion. A panel of the Federal Circuit Court of Appeals affirmed the district court's ruling on its separate written description requirement. App., *infra*, 1a-30a. The court rejected Petitioner's argument that "no written description requirement exists independent of enablement" under 35 U.S.C. § 112. App., *infra*, 8a. The court held that, in addition to including a written description of the invention that meets the statutory requirement of "enabl[ing] persons skilled in the art to" make and use the claimed invention, a patent must meet a separate written description requirement, which the court described in various ways, including as a requirement that the description establish that the applicant has possession of the invention.

The court declared that its separate written description requirement has always existed and, as announced in *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), serves as a general disclosure requirement separate from enablement under § 112. The court also declared that the separate description requirement applies to all manner of invention. App., *infra*, 16a-20a.

The court recognized that Petitioner's '850 patent contains: (1) descriptions of Cox-1 and Cox-2; (2) descriptions of how to make cells that express Cox-1 or Cox-2, but not both; (3) screening assays (tests) to identify compounds that selectively inhibit Cox-2; and (4) methods of treatment using such compounds. App., *infra*, 23a. The court held that the '850 patent, nonetheless, does not meet the separate written description requirement because it "does not disclose any compounds that can be used in its claimed methods," and "[t]he claimed methods thus cannot be practiced based on the patent's specification. . . ." *Id.* at

23a-24a. The court concluded that, "[w]ithout such disclosure, the claimed methods cannot be said to have been described." *Id.* at 24a.

In light of its affirmance on written description grounds, the court did not decide the enablement issue – that is, whether the written description is sufficient to enable persons skilled in the art to make and use the invention. App., *infra*, 28a.

c. Opinions on denial of rehearing *en banc*. On July 2, 2004, the court of appeals denied rehearing *en banc* in a 7 to 5 vote. App., *infra*, 69a-122a. The decision provoked 4 of the dissenting judges to join or write strongly written dissents, each of which acknowledged that the Federal Circuit's written description jurisprudence is in complete disarray, and that the fundamental question of whether § 112, ¶ 1 contains a written description requirement separate from a written description requirement for the purpose of enablement is ripe for resolution. App., *infra*, 71a-73a; 78a-122a.

Judge Newman, dissenting "from the court's decision not to resolve en banc the burgeoning conflict in pronouncements" by different panels of the Federal Circuit, App., *infra*, 71a, explained:

> This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products. The appropriate forum is now the en banc tribunal, not continuing debate in panel opinions applying divergent law.
>
> * * *
>
> The issue of whether patent law contains a separate written description requirement has percolated through various panels of this court, on a variety of facts. . . . This question has percolated enough; it is ripe for en banc resolution.

App., *infra*, 71a, 73a.

In a second opinion dissenting from denial of rehearing *en banc*, Judge Rader, joined by Judges Gajarsa and Linn, criticized the court's refusal "to clarify and correct its confusing jurisprudence on the new written description invalidity doctrine" via *en banc* review. App., *infra*, 78a. Judge Rader stated that the separate written description requirement is "contrary to logic and the statute itself," "conflicts with binding precedent," "engendered confusion," and "changes the established rules of claiming and disclosing inventions." *Id.* at 78a, 79a n.2, 82a and 91a.

Analyzing precedential case law and the evolution of § 112, ¶ 1 from 1793 to present, Judge Rader concluded that "the *Eli Lilly* doctrine has no basis in the written description language of the original Patent Act," and "the statutory language of 35 U.S.C. § 112, ¶ 1 has not changed in any way that justifies 'discovery' of a vast new validity doctrine over two hundred years after the 1793 Act." *Id.* at 85a. Judge Rader also examined Federal Circuit case law following the *Lilly* decision, and attached a lengthy appendix listing dozens of scholarly legal works, all of which highlight the persistent confusion regarding the written description requirement of § 112. *Id.* at 79a-82a, 93a-117a.

In the third opinion dissenting from denial of rehearing *en banc*, Judge Linn, joined by Judges Rader and Gajarsa, declared that the decision of the panel below "perpetuates the confusion our precedent . . . has engendered in establishing 'written description' as a separate requirement of 35 U.S.C. § 112, ¶ 1, on which a patent may be held invalid." App., *infra*, 118a. The opinion flatly declared: "[t]hat precedent should be overturned." *Id.* Judge Linn emphasized that the Federal Circuit's internal debate:

> continues to leave uncertain how inventions are protected, how the United States Patent and Trademark Office discharges its responsibilities, and how business is conducted in emerging fields of law. *These uncertainties will remain unless resolved by [the Federal Circuit] en banc or by the*

> *Supreme Court.* The issue is important, is ripe for consideration, and deserves to be clarified, one way or the other.

App., *infra*, 122a (emphasis added).

REASONS FOR GRANTING THE PETITION

The opinions by the various members of the Federal Circuit dissenting from that court's order denying rehearing *en banc* amply set forth the reasons that further review is warranted in this case. The judges of the Federal Circuit are in disagreement on the issue of whether a separate written description requirement exists under 35 U.S.C. § 112, apart from the requirement that the written description enable one skilled in the art to make and use the invention.

The judgment below (1) perpetuates a flawed construction of 35 U.S.C. § 112, ¶ 1; (2) eviscerates the statutory presumption of validity in 35 U.S.C. § 282 by adopting a written description requirement that is not tied to evidence of the knowledge of people skilled in the art; and (3) radically transforms the patent statute to favor industry over basic researchers, thereby severely undercutting the operation of the Bayh-Dole Act, 35 U.S.C. §§ 200-212, and the policies underlying that Act.

Review by this Court is now necessary because the Federal Circuit has declined to resolve the issue through *en banc* review, over strong objections of several members of that court. Because panels of the Federal Circuit are bound by the holding of prior panel opinions, a formal split within the Circuit is not permitted. Moreover, because the Federal Circuit has exclusive jurisdiction of patent appeals from district courts, there can be no inter-circuit conflict on this question of the correct construction and application of the provision of the Patent Act at issue. Nor is it possible for the issues presented by this case to be ventilated in other Circuits, even though the Federal Circuit's erroneous analysis violates basic principles of statutory construction.

The vigorous dissents by a significant number of the Federal Circuit judges from the denials of rehearing *en banc* in this and an earlier case serve a function similar to the inter-circuit percolation that often precedes this Court's review. The several opinions below have thoroughly explored the issues presented by this case. As Judge Newman remarked, "[t]he differences of opinion among the judges of the Federal Circuit, are, in microcosm, the 'percolation' that scholars feared would be lost by a national court at the circuit level. . . . This question has percolated enough. . . ." App., *infra*, 73a.

A. The Federal Circuit Is Deeply Divided Over Whether 35 U.S.C. § 112 Contains A Written Description Requirement Separate From Enablement

1. The Genesis of the Federal Circuit's Separate Written Description Requirement

The controversy underlying this case has roots that date back to a decision by the Federal Circuit's predecessor court, the Court of Customs and Patent Appeals, in *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967). Contrary to the plain language of 35 U.S.C. § 112, ¶ 1, the *Ruschig* court interpreted § 112 to contain two distinct written description requirements: (1) the well-understood requirement that a patent contain a written description of the invention (and the manner and process of making it and using it) sufficient "to enable any person skilled in the art to which it pertains . . . to make and use the same" (the "enablement requirement"); and (2) a new and ill-defined requirement that later-claimed inventions must be sufficiently described by an earlier application in order to take the benefit of that earlier application's filing date (the "separate written description requirement"). The *Ruschig* court created this second written description requirement in the context of determining whether new claim language present in the application at issue was entitled to priority

to an earlier application under 35 U.S.C. § 120. *See Ruschig*, 379 F.2d at 991, 994-96.

For the next 30 years, the notion that § 112, ¶ 1 contains a separate written description requirement appeared sporadically in Court of Customs and Patent Appeals and Federal Circuit opinions. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319-20 (Fed. Cir.) (per curiam), *cert. denied*, 124 S. Ct. 464 (2003) (discussing evolution of separate written description requirement); *id.* at 1323-24 (Rader, J., concurring) (same). During this period, the C.C.P.A. and Federal Circuit used the separate written description requirement solely to prevent applicants from introducing new material into their patents while claiming the benefit of applications filed at an earlier date. *Id.* at 1324. "Thus, from 1967 until 1997, . . . the innovative new reading of § 112, operated only to determine whether new claim language deserved priority back to the patent's original filing date." *Id.*

The use of this "separate written description requirement" in this context – to police priority assertions – was not supported by the plain language of § 112. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 977-78 (Fed. Cir. 2002) (Rader, J., dissenting). And, indeed, during this period the Federal Circuit acknowledged that there was confusion in its "decisions concerning the extent to which the 'written description' requirement is separate and distinct from the enablement requirement." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

But although controversial and confusing, it was recognized that the use of the separate written description "requirement" to police priority was "synonymous" with another provision of the statute, 35 U.S.C. § 132, which prohibits "new matter" from being introduced into the claims or specification of a patent. *Moba, B.V.*, 325 F.3d at 1319 (citing *In re Rasmussen*, 650 F.2d 1212, 1214 (C.C.P.A. 1981)). Therefore, the separate written description requirement to police priority "did no harm." *Id.* at 1324 (Rader, J., concurring).

The situation changed, however, in 1997 when a panel of the Federal Circuit decided *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and "inexplicably wrote a new disclosure requirement, found nowhere in title 35, and attributed that new requirement to the written description doctrine." *Moba, B.V.*, 325 F.3d at 1324 (Rader, J., concurring). *Lilly* applied its new written description standard for patentability not to police priority, but rather to invalidate originally-filed claims to DNA. *Id.* at 1320. "Invoking § 112, *Lilly* required a precise definition of a DNA sequence in the patent specification." *Moba, B.V.*, 325 F.3d at 1320. The *Lilly* panel found that a patent's written description that enabled persons skilled in the art to obtain the claimed DNA was nonetheless insufficient to meet its new written description requirement under § 112. *Lilly*, 119 F.3d at 1566-67. The *Lilly* panel thereby created a rigid new disclosure requirement for compliance with § 112 for DNA patents, via this second, untethered, written description requirement. *Lilly* rendered a patent for DNA *per se* invalid if it did not meet that standard, even if it enabled a skilled person to make and use the invention.

2. The Federal Circuit's Creation of a Separate Written Description Requirement for Patentability Has Created Confusion and Divided that Court

Decisions of the Federal Circuit in the wake of *Lilly* made clear that there was and remains a deep schism among the judges of the Federal Circuit on the issue of whether § 112 contains a second written description requirement separate from enablement and, if so, what the requirement is, and how (if at all) it should be applied to all inventions. *See Moba, B.V.*, 325 F.3d at 1322-27 (Rader, J., concurring); *id.* at 1327-28 (Bryson, J., concurring). *See also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003); *id.* at 1361 (Clevenger,

J., dissenting); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000); *id.* at 1002-05 (Lourie, J., dissenting); *SunTiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1337-38 (Fed. Cir. 1999) (Lourie, J., dissenting). As Judge Newman remarked, "Federal Circuit law of written description has become encumbered with inconsistent pronouncements. . . ." App., *infra*, 73a.

The inconsistency includes the failure of the Federal Circuit judges to come to agreement about the reach and application of the new written description requirement set forth in *Lilly*. Prior to the instant case, *Lilly* was widely regarded as announcing a special rule for biotechnology inventions (App., *infra*, 98a, 100a, 102a-103a, 105a-107a, 113a) and, even in that context, was considered to be "on the decline." *Moba, B.V.*, 325 F.3d at 1326 (Rader, J., concurring). The opinion below, however, breathed new life into *Lilly*, and dramatically expanded its reach, declaring it to be the legal standard for patentability that applies to "all types of inventions." App., *infra*, 18a.

In his dissent from denial of rehearing *en banc* below, Judge Rader also pointed out that the United States, as *amicus curiae* requesting *en banc* reconsideration in *Enzo Biochem*, had "issued a call for clarity" which the Federal Circuit "has yet to address." *Id.* at 81a. Judge Rader quoted the United States' brief, which noted that the Federal Circuit's numerous decisions on the written description requirement of § 112 "have not taken a clear and uniform position regarding the purpose and meaning of the requirement," and that "inventors, the public, and the USPTO" would benefit from "an authoritative interpretation of the provision." App., *infra*, 81a-82a (quoting Brief of *Amicus Curiae* United States in *Enzo Biochem*, No. 01-1230 at 4-5, 9).

The conflict and its ramifications are so severe that in this case and in *Enzo Biochem*, 323 F.3d 956, a significant minority of the judges called for *en banc* resolution of this issue of statutory construction. App., *infra*, 71a-122a. Indeed, in the instant case, Judge Bryson, who was a member of the panel that invalidated petitioner's patent on written description grounds, voted with Judges Newman, Rader, Linn and Gajarsa to rehear this case *en banc*. App., *infra*, 78a. Judge Bryson was a member of the *Lilly* panel (as was Judge Newman), but also has expressed the view that "[p]erhaps the entire line of cases stemming from *Ruschig* is wrong," and "perhaps we should at some point address that question en banc." *Moba, B.V.*, 325 F.3d at 1328 (Bryson, J., concurring). The "real question," Judge Bryson has explained, "is not whether *Lilly* was an unwarranted departure from the *Ruschig* line of cases, but whether that entire line of cases is based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1." *Id.* As Judge Bryson's vote to hear petitioner's case *en banc* indicates, petitioner's case is the appropriate case in which to address that fundamental question.

The current division in the Federal Circuit indicates that the issue has gone as far as it can in the Federal Circuit. The academic community has also thoroughly examined the question and produced an extensive body of scholarly literature, predominantly critical of the Federal Circuit's position. App., *infra*, 93a-117a. The time is thus ripe for this Court's review. Indeed, three Federal Circuit judges emphasized that the uncertainties will remain unless this Court steps in now to resolve this fundamental issue. App., *infra*, 122a.

B. The Panel Below Is Wrong That 35 U.S.C. § 112 Imposes A Written Description Requirement That Is Separate From The Requirement That The Written Description Enable Persons Skilled In The Art To Make And Use The Invention

1. The Plain Language of the Statute and its Structure and History Demonstrate the Court of Appeals' Error of Statutory Construction

a. The Federal Circuit's interpretation of 35 U.S.C. § 112 to create a written description requirement that is not tied to enablement ignores ordinary grammar and syntax, and thus disregards the plain language of the statute.

As this Court has made clear, "[i]n cases of statutory construction" the analysis must begin "with the language of the statute." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). "[U]nless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." *Id.* (citation omitted). The Court has been particularly attentive to this requirement of statutory construction with regard to interpretation of the Patent Act. The Court has expressly cautioned against "read[ing] into the patent laws limitations and conditions which the legislature has not expressed." *Id.* (citation omitted). Yet that is precisely what the Federal Circuit has done in this case.

The plain meaning of the first paragraph of § 112 is manifest. "Section 112, first paragraph, is a simple sentence, with a comma after 'it,' making the phrase 'in such full . . . the same' a modifier of both objects of the verb 'contain.' All before that comma prescribes *what* shall be described. The phrase following the comma prescribes *how* and for *whom* it shall be described." *In re Barker*, 559 F.2d 588, 594-95 (C.C.P.A. 1977) (Markey, J., dissenting) (emphasis in original). As Chief Judge Markey further explained: Congress specified "in a single prepositional

phrase, that the description of the invention, and the description of the manner of making and using it, shall *both* be in 'such full, clear, concise, and exact terms as to enable'" a person skilled in the art to make and use the invention. *Id.*; *see also Enzo Biochem,* 323 F.3d at 976 (Rader, J., dissenting) ("[A]n adequate written description assures that others can 'make and use' the invention") (citation omitted). In other words, in drafting the Patent Act, Congress logically tied written description to a subject ("the invention" and "the manner and process of making and using it") for a purpose ("to enable any person skilled in the art . . . to make and use the same").

In a prior case, the United States, speaking with the concurrence of the United States Patent and Trademark Office, the agency charged with examining and issuing patents consistent with the patent laws, has likewise acknowledged that the statutory language does not support imposition of a written description requirement that is separate from and more demanding than enablement: "A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention." App., *infra*, 84a n.5 (quoting Brief of *Amicus Curiae* United States in *Enzo Biochem*, No. 01-1230 at 5).

b. This straightforward reading of § 112 is fully supported by the structure and history of the Patent Act. *See* App., *infra*, 82a. The "written description" language originated in the Patent Act of 1793. 1 Stat 318. The original Act required that a patentee

> deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, *as to distinguish the same from all other things before known*, and to enable any person skilled in the art or science, of which it is a branch . . . to make, compound, and use the same.

1 Stat. 318 (sec. 3) (emphasis added).

The purpose of this original written description language was twofold. First, it enabled those "skilled in the art or science, of which it is a branch . . . to make, compound and use the [invention]." 1 Stat. 318. Second, because the Patent Act of 1793 did not require inclusion of claims in a patent, the original requirement that the written description of an invention "distinguish the same from all other things before known" served the function that patent claims now serve, *i.e.*, to delineate the boundaries of what the patentee regards as his or her invention. Thus, the original provision required an applicant to put the public on notice of "what the party claims as his own invention." *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822).

In 1836, Congress amended the Patent Act to require that claims be included in a patent application: a patentee was required to "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery." 5 Stat. 117 (section 6). As a reflection of this new claim requirement, the "written description" phraseology was modified to read:

> [An inventor] shall deliver a written description of his [invention], and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains . . . to make, construct, compound, and use the same. . . .

5 Stat. 117 (section 6). The requirement that the written description "distinguish the [invention] from all other things before known" was removed. With separately required claims to delineate the boundaries of the invention, the sole function left to the written description in the specification was, and is, to enable the skilled scientist to make and use the invention.

Indeed, the Federal Circuit has never articulated why, if the statute contains a written description requirement

for the validity of a patent that is separate from and more demanding than enablement, Congress would ever have bothered with the clear statutory requirement that there also be a written description for purposes of enablement.

2. There Is No Need for a Separate Written Description Requirement

Not only is a separate written description requirement unsupported by the plain meaning and history of § 112, it is an invented requirement for patentability for which there is no identifiable need. *Moba, B.V.*, 325 F.3d at 1326, n.6 (Rader, J., concurring). It is telling that "neither the Federal Circuit nor the C.C.P.A. has ever articulated a persuasive rationale for distinguishing the written description requirement from the enablement requirement." Mark D. Janis, *On Courts Herding Cats: Contending with the Written Description Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 Wash. U. J. L. & Pol'y 55, 62-69 (2000).

Panels of the Federal Circuit have claimed that a separate description requirement is necessary to "convey a detailed identity of an invention." App., *infra*, 14a; *see also Enzo*, 323 F.3d at 963-64. But the court has never identified what "detailed identity" is lacking in a patent that fulfills the enablement requirement of § 112, ¶ 1, and the requirement of claims of § 112, ¶ 2. *See Moba, B.V.*, 325 F.3d at 1326 (Rader, J., concurring); Janis, *supra*, at 67-69. A specification that fully enables a definitely claimed invention already conveys possession of that invention – it conveys that the inventor "invented what is claimed" and there is no need for additional description. *Moba, B.V.*, 325 F.3d at 1327 (Rader, J., concurring).

Moreover, manipulating what Congress has clearly written in the statutory text is wholly unnecessary to fulfill the policies underlying the Patent Act. Enablement masterfully serves the *quid pro quo* that is the foundation for the limited monopoly contemplated by the Constitution.

A patentee is granted the exclusive rights to his or her invention for a specified amount of time. In exchange for that limited monopoly, the patentee must provide a sufficient disclosure of his invention such that "upon the expiration of that period, the knowledge of the invention inures to the people, who are thus *enabled* without restriction to practice it and profit by its use." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933) (emphasis added). That is precisely what petitioner did in this case.

C. The Federal Circuit's Misinterpretation Of § 112 To Create A Written Description Requirement Separate From Enablement Has Serious And Widespread Adverse Consequences

1. The Federal Circuit's Reading of § 112 Dispenses With The Perspective of "Persons Skilled in the Art" and in so Doing, Eviscerates the Statutory Presumption of Validity

Pursuant to 35 U.S.C. § 282, issued United States patents "shall be presumed valid." This presumption entitles a patent holder to prevail unless and until clear and convincing evidence of invalidity is introduced. *Magnavision, Inc. v. Bonneau Co.*, 115 F.3d 956, 958 (Fed. Cir. 1997). In the instant case, however, Respondents presented *no* relevant evidence of invalidity to support their summary judgment motions. Instead, Respondents asserted that the presumptively valid '850 patent itself was evidence of its own invalidity sufficient to overcome the statutory presumption and the Federal Circuit panel agreed. App., *infra*, 29a.

To arrive at this conclusion, the panel dispensed with the statutorily-required perspective of persons skilled in the art. Instead, the court applied a rigid rule for compliance with its "separate written description requirement" that rendered the '850 patent *per se* invalid because it did not describe the exact chemical formula of an implementing compound. That construction of § 112 (to require a

written description that does more than enable) vitiates the presumption of validity because it allows a court to invalidate a patent, as the court below did, notwithstanding unrefuted evidence that the patent's specification enables persons skilled in the art to make and use the claimed inventions.

In finding the '850 patent invalid on its face for failure to meet the written description requirement, the Federal Circuit upset Congress's clear intent that the adequacy of a patent's written description be measured by the knowledge of a "person skilled in the art," and not by the layperson's knowledge of a judge. *See W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556 (Fed. Cir. 1983) ("Patents . . . are written to enable those skilled in the art to practice the invention, not the public."); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997) (discussing perspective of a skilled practitioner in terms of informing a fact-finder about the interchangeability of elements). The question of enablement is based on "numerous factual underpinnings," including the state of the art, and the knowledge and skill of practitioners in the art. *Gould v. Quigg*, 822 F.2d 1074, 1077 (Fed. Cir. 1987). Enablement looks not to the face of the patent or to a judge's own knowledge, but to what "persons skilled in the art" can do with the patent's written description. Thus, by requiring that compliance with § 112, ¶ 1 be measured by the knowledge of persons skilled in the art, Congress assigned to the fact-finder the important role of ascertaining the sufficiency of a patent's written description.

Under the statutory scheme crafted by Congress, it is not possible to overcome the presumption of § 282 by challenging the validity of a patent on enablement grounds, without the introduction of *some* evidence that suggests "a person skilled in the art" would not be able to take the patent's specification, along with the knowledge of skilled artisans, and make and use the invention without undue experimentation. Under the standard Congress has chosen, a judge's own reading of the patent is not an

acceptable substitute for such *evidence* of those skilled in the art.

Thus, the district court fundamentally erred in entering summary judgment against Petitioner on written description (as well as enablement) despite the fact that (1) Respondent introduced no evidence of the perspective of persons skilled in the art; (2) Petitioner introduced substantial evidence supporting its opposition to summary judgment on those issues; and (3) Petitioner enjoys a statutory presumption of validity under 35 U.S.C. § 282. The sum of Petitioner's evidence demonstrated that the written description in the '850 patent enables persons of skill to practice Petitioner's claimed methods of treatment. That evidence, however, was wholly disregarded by the court in its application of its *per se* requirement that the patent's written description include a description of the exact chemical formula of a compound used to practice the methods of treatment.

2. The *Per Se* Invalidation of Patents That Do Not Meet the Federal Circuit's New and More Demanding Written Description Requirement Disrupts the Settled Expectations of the Inventing Community

The decision below, following the *Lilly* decision and expanding it beyond biotechnology patents, dramatically "changes the established rules of claiming and disclosing inventions," App., *infra*, 91a, thereby "disrupt[ing] the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

Lilly elevated written description from a priority doctrine redundant with § 132 (which prohibits the introduction of new matter), into a new patentability doctrine. Moreover, by requiring that claims to DNA be described by specific chemical structure, *Lilly* for the first time required a patent to meet a written description standard not

measured by the ability to enable one skilled in the art to make and use the invention. As Judge Rader explained, "[b]efore the 1997 change [announced in *Lilly*], no inventor could have foreseen that the Federal Circuit would make a new disclosure rule." App., *infra*, 91a. *Lilly* thus upset patent holders' expectations because "[w]ithout any way to redraft issued patents to accommodate the new rule, many patents in the field of biotechnology face[d] serious and unavoidable validity challenges" merely because the patent drafter may not have recited the exact chemical structure of DNA. *Id.*; *see also Moba, B.V.*, 325 F.3d at 1325 (Rader, J., concurring).

The decision below wreaks further havoc on the settled expectations of the inventing community. It expands to "all fields of emerging technology," the separate written description requirement of *Lilly* and its rigid rule for a detailed structural description, irrespective of the knowledge and understanding of persons skilled in the art. App., *infra*, 121a. Indeed, disregarding the state of the art, and the knowledge and understanding of persons skilled in the art, the panel in the instant case mandated that petitioner set forth the exact chemical formula of a compound in the claimed methods because describing the compound by its function and enabling skilled artisans to practice the claimed methods was considered insufficient. In doing so, the Federal Circuit, despite its protestations to the contrary, effectively requires that an inventor reduce to practice an invention before the inventor can file a patent application. App., *infra*, 21a. Applied to other fields, the holding would require, for example, a software patent to disclose *every* line of computer code for any program utilized in the invention. *See id.* at 91a (Rader, J., dissenting from denial of rehearing *en banc*).

The consequences of the Federal Circuit's decision thus are serious and widespread. Inventors in every area of technology who have followed decades of precedent in

describing their inventions may find themselves holding invalid patents.

This is an outcome that this Court has repeatedly denounced. For example, in *Festo*, this Court rejected the Federal Circuit's adoption of a post hoc "per se rule" that would have barred patentees from asserting infringement under the doctrine of equivalents of claims amended (for whatever reason) during patent prosecution. This Court explained:

> The petitioner in *Warner-Jenkinson* requested another bright-line rule that would have provided more certainty in determining when [prosecution history] estoppel applies but at the cost of disrupting the expectations of countless existing patent holders. We rejected that approach: *"To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision."*

Festo, 535 U.S. at 739 (citation omitted) (emphasis added).

The adoption by the court of appeals in the instant case of a rigid "separate written description requirement" that renders a patent invalid *per se* if it fails to include the exact chemical formula of a compound, even when the written description meets the statutory enablement standard, constitutes another such rule that should be rejected to avoid disruption.

3. The Federal Circuit's Ruling Deprives Petitioner and Other Research Institutions and Inventors Who Perform Basic Research of Patent Protection for Their Discoveries

Under the ruling below, it will be impossible to obtain patent protection for a claim to a new method of treatment

without describing the exact chemical formula of a compound to be used in that method. This dramatically rewrites § 112 so as to preclude patenting inventions founded on basic research. Thus, one can discover and describe (a) a new and advantageous method of treating disease, and (b) how to identify compounds that can be used in the new method, but unless one also describes the exact chemical formula of a pill to be ingested, one cannot obtain patent protection for the invention.[3]

Moreover, by requiring inventors to actually practice their inventions, *i.e.*, to create a compound, before applying for a patent application, the Federal Circuit's written description rule discourages early disclosure of inventions. The Patent Act requires inventors to file their patent applications within one year of publicly disclosing their invention. 35 U.S.C. § 102(b). The new rule, however, forces inventors to wait until they have actually reduced their inventions to practice before seeking patent protection. Inventors will thus delay making a public disclosure of pioneering inventions and discoveries until they have reduced the invention to practice, or are certain to be close to doing so, because once they make the disclosure, the one-year clock starts running. Moreover, inventors will be required to "spend their valuable time and resources fleshing out all the obvious variants of their last invention instead of pursuing their next significant advance in the useful arts." App., *infra*, 91a (Rader, J., dissenting from denial of rehearing *en banc*).

Patent law, however, recognizes the value of pioneering basic research and early disclosure of that research. "A policy in favor of prompt disclosure is particularly appropriate in the case of pioneer patents, where publication of

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[3] It is well-settled, of course, that novel methods – not just compositions of matter – are patentable subject matter. 35 U.S.C. § 101.

a novel invention is all the more likely to stimulate others. '[B]asic inventions have led to basic patents, which amounted to real incentives, not only to invention and its disclosure, but its prompt, early disclosure.'" *Studiengesellschaft Kohle mbH v. Dart Indus., Inc.*, 549 F. Supp. 716, 743 (D. Del. 1982), *aff'd*, 726 F.2d 724 (Fed. Cir. 1984) (quoting *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977)); *see also In re Koller*, 613 F.2d 819, 824-25 (C.C.P.A. 1980) (noting that pioneers "deserve broad claims" to the "broad concept.") (citation omitted).

4. The Decision Below Undermines the Goals and Policies of the Bayh-Dole Act of 1980

The rise of the American research university is one of the most important developments of the latter half of the twentieth century. Modern research universities grew out of the partnership between the federal government and universities fashioned in the aftermath of World War II.

Congress designed the Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212, to foster a partnership between research institutions and industry, and thereby stimulate U.S. innovation and bring new technologies to the public. In crafting the Bayh-Dole Act, Congress recognized that innovative breakthroughs are frequently the product of federally-funded university research and that, although universities are well-suited to accomplish such basic research, private industry is best suited to commercialize new technologies. The goal of the Bayh-Dole Act was to effectuate the transfer of pioneering breakthroughs resulting from basic research to industry, which would commercialize the technology and bring new products to market.

The Bayh-Dole Act uses the patent system to achieve these goals. Under Bayh-Dole, ownership of discoveries and inventions arising out of federally-funded research is vested in the institutions carrying out the research. Such institutions can obtain patents on newly-discovered technology, and license those patents to the private sector. Bayh-Dole thus provides incentives to universities to patent and market their inventions, and incentives to industry (via rights to new technology) to invest in and commercialize early-stage technology.

The decision below marks a fundamental shift in the types of innovation that the law recognizes as patentable. By requiring an actual reduction to practice, the decision below seriously diminishes the ability of universities and research institutions to obtain patents on early-stage technology founded upon basic research, which is a fundamental feature of the Bayh-Dole paradigm. This in turn eliminates industry's prospect of obtaining rights to the technology which is the primary incentive for it to invest in, and undertake commercial development of, basic inventions. Protection of early stage invention, furthermore, is very important to technology-based start-up companies. With the decision below, the Bayh-Dole paradigm breaks down and its purpose of rapidly bringing new technologies to the public is substantially undermined.

The Bayh-Dole Act and 35 U.S.C. § 112 work in harmony only if § 112 is interpreted as Congress intended, to contain a written description requirement that a patent specification enable persons skilled in the art to make and use the claimed invention, nothing more and nothing less.

CONCLUSION

For the reasons set forth above, the petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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SEPTEMBER 30, 2004

APPENDIX A

UNIVERSITY OF ROCHESTER, Plaintiff-Appellant, v. G.D. SEARLE & CO., INC., MONSANTO COMPANY, PHARMACIA CORPORATION, and PFIZER INC., Defendants-Appellees.

03-1304

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

358 F.3d 916; 2004 U.S. App. LEXIS 2458; 69 U.S.P.Q.2D (BNA) 1886

February 13, 2004, Decided

COUNSEL: Gerald P. Dodson, Morrison & Foerster, LLP, of Palo Alto, California, argued for plaintiff-appellant. With him on the brief were Emily A. Evans, Erica D. Wilson, and Erik J. Olson. Of counsel on the brief was Jeanine Arden Ornt, Office of Counsel, University of Rochester, of Rochester, New York.

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APPEALED FROM: United States District Court for the Western District of New York.

JUDGES: Before LOURIE, BRYSON, and DYK, Circuit Judges.

OPINION BY: LOURIE

OPINION: LOURIE, Circuit Judge.

The University of Rochester ("Rochester") appeals from the decision of the United States District Court for the Western District of New York granting summary judgment that United States Patent 6,048,850 is invalid. *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003). Because we conclude that the court did not err in holding the '850 patent invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment on that ground, we affirm.

BACKGROUND

Traditional non-steroidal anti-inflammatory drugs ("NSAIDs") such as aspirin, ibuprofen, ketoprofen, and naproxen are believed to function by inhibiting the activity of enzymes called cyclooxygenases. Cyclooxygenases catalyze the production of a molecule called prostaglandin H_2, which is a precursor for other prostaglandins that perform various functions in the human body. *Id.* at 219.

In the early 1990s, scientists discovered the existence and separate functions of two distinct cyclooxygenases,

referred to as "COX-1" and "COX-2."[1] COX-1 is expressed (*i.e.*, produced biologically) in the gastrointestinal tract, where it is involved in the production of prostaglandins that serve a beneficial role by, for example, providing protection for the stomach lining. *Id.* COX-2 is expressed in response to inflammatory stimuli, and is thought to be responsible for the inflammation associated with diseases such as arthritis. *Id.* It is now known that the traditional NSAIDs inhibit both COX-1 and COX-2, and as a result they not only reduce inflammation, but also can cause undesirable side effects such as stomach upset, irritation, ulcers, and bleeding. *Id.*

After the separate functions of COX-1 and COX-2 were discovered, it was hypothesized that it would be possible to reduce inflammation without gastrointestinal side effects if a method could be found for selectively inhibiting the activity of COX-2 (*i.e.*, inhibiting the activity of COX-2 without inhibiting COX-1 activity). *Id.* To that end, Rochester scientists developed a screening assay for use in determining whether a particular drug displayed such selectivity, and filed a U.S. patent application directed to their developments in 1992. After filing a series of continuation, continuation-in-part, and divisional applications derived from that 1992 application, the scientists eventually received United States Patent 5,837,479 in 1998, covering methods "for identifying a compound that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2)."

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[1] COX-1 and COX-2 are alternatively referred to as "PGHS-1" and "PGHS-2," respectively, where "PGHS" is an abbreviation for "prostaglandin H synthase."

From a division of the application that led to the '479 patent, the scientists also obtained, on April 11, 2000, the '850 patent. The '850 patent contains three independent claims and five dependent claims. The three independent claims read as follows:

> 1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits its activity of the PGHS-2 gene product to a human host in need of such treatment.
>
> 5. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits its activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the activity of the non-steroidal compound does not result in significant toxic side effects in the human host.
>
> 6. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits its activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the ability of the non-steroidal compound to selectively inhibit the activity of the PGHS-2 gene product is determined by:
>
> > a) contacting a genetically engineered cell that expresses human PGHS-2, and not human PGHS-1, with the compound for 30 minutes, and exposing the cell to a pre-determined-amount of arachidonic acid;
> >
> > b) contacting a genetically engineered cell that expresses human PGHS-1, and

> not human PGHS-2, with the compound for 30 minutes, and exposing the cell to a pre-determined amount of arachidonic acid;
>
> c) measuring the conversion of arachidonic acid to its prostaglandin metabolite; and
>
> d) comparing the amount of the converted arachidonic acid converted by each cell exposed to the compound to the amount of the arachidonic acid converted by control cells that were not exposed to the compound, so that the compounds that inhibit PGHS-2 and not PGHS-1 activity are identified.

'850 patent, col. 71, l. 36 – col. 72, l. 51. Thus, all eight claims are directed to methods "for selectively inhibiting PGHS-2 activity in a human host" by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment."

On the day the '850 patent issued, Rochester sued G.D. Searle & Co., Inc., Monsanto Co., Pharmacia Corp., and Pfizer Inc. (collectively, "Pfizer"), alleging that Pfizer's sale of its COX-2 inhibitors Celebrex® and Bextra® for treatment of inflammation infringed the '850 patent,[2] and

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[2] Celebrex® and Bextra®, generically known as celecoxib and valdecoxib, respectively, were both developed by Searle, which was purchased by Monsanto in 1985. In 2000, Monsanto merged with Pharmacia & Upjohn, Inc. to form Pharmacia Corp. In 2002, Monsanto, sans Searle, was spun off from Pharmacia, and Pharmacia merged with Pfizer in 2003. The combined company has retained the name Pfizer Inc.

seeking injunctive and monetary relief. *Univ. of Rochester,* 249 F. Supp. 2d at 220. In May 2002, Pfizer moved for summary judgment of invalidity of the '850 patent for failure to comply with the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1. Rochester opposed the motion and filed a cross-motion for summary judgment with respect to the written description issue. *Id.*

In evaluating the parties' motions, the district court found that, although all of the claims require the use of a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene," the '850 patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research. *Id.* at 224-25, 228-29. Indeed, the court found no evidence in the '850 patent that the inventors themselves knew of any such compound at the time their patent application was filed. *Id.* at 228. Accordingly, the court concluded that the patent's claims are invalid for lack of written description. *Id.* at 224.

The district court also found that practice of the claimed methods would require "a person of ordinary skill in the art . . . to engage in undue experimentation, with no assurance of success," and on that basis concluded that the claims are also invalid for lack of enablement. *Id.* at 232. The court considered, but rejected as conclusory, Rochester's experts' opinions that one of skill in the art would have known to start with existing NSAIDs and would have used routine methods to make structural changes to lead compounds to optimize them, citing a general failure to point to any language in the patent supporting those opinions. *Id.* at 233.

Finding no genuine issue of material fact concerning either written description or enablement, the district court accordingly granted Pfizer's motions for summary judgment of invalidity of the '850 patent for failure to meet the written description and enablement requirements, denied Rochester's cross-motion, and dismissed the complaint. *Id.* at 235-36.

Rochester now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Rochester asserts three grounds of error on appeal. First, it argues that the district court erred by granting Pfizer's motion for summary judgment of invalidity for lack of written description. Second, it argues that the court erred by granting Pfizer's motion for summary judgment of invalidity for lack of enablement. Third, Rochester contends that the court erred by denying its cross-motion for summary judgment with regard to written description. Pfizer refutes each of those asserted grounds of error.

Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1353 (Fed. Cir. 1998). We review a district court's grant of summary judgment *de novo*, reapplying the summary judgment standard. *Conroy v. Reebok Int'l*, 14 F.3d 1570, 1575 (Fed. Cir. 1994). In contrast, "when a district court *denies* summary judgment, we review that decision with considerable deference to the court," and "will not disturb the trial court's denial . . . unless we find that the court has indeed abused its discretion in so denying." *Suntiger,*

Inc. v. Scientific Research Funding Group, 189 F.3d 1327, 1333 (Fed. Cir. 1999). Additionally, "[w]hen evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 962 (Fed. Cir. 2001) ("*Barr*"). In that process, we draw all justifiable inferences in the nonmovant's favor. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 255 (1986).

An issued patent enjoys a presumption of validity, 35 U.S.C. § 282, that can be overcome only through clear and convincing evidence, *U.S. Surgical Corp. v. Ethicon, Inc.,* 103 F.3d 1554, 1563 (Fed. Cir. 1997). Accordingly, a party "seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity." *Barr,* 251 F.3d at 962.

In its first argument, Rochester asserts that the district court effectively – but erroneously – held that a patent claiming a method of obtaining a biological effect in a human by administering a compound cannot, as a matter of law, satisfy the written description requirement without disclosing the identity of any such compound. Indeed, Rochester contends that "no written description requirement exists independent of enablement." In any event, Rochester argues that its patent met the requirements of § 112 and is not invalid.[3]

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[3] Rochester is supported by *amici curiae* the Regents of the University of California, the University of Texas Southwestern Medical Center at Dallas, and the University of Texas M.D. Anderson Cancer Center, which make essentially the same points.

Pfizer responds to Rochester's argument by pointing out that we have "interpreted § 112 'as requiring a "written description" of an invention separate from enablement,'" (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002)), and that "the many prior precedential decisions" contrary to Rochester's position "cannot be overruled except by an *en banc* decision." Pfizer also cites *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), in which we explained that "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]," *id.* at 1563; and *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed. Cir. 2000), in which we stated that the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification," *id.* at 1345. Pfizer asserts that a patent fails to satisfy the written description requirement if it claims a method of achieving a biological effect, but discloses no compounds that can accomplish that result. It maintains that the district court correctly invalidated Rochester's '850 patent.[4]

We agree with Pfizer that our precedent recognizes a written description requirement and that the '850 patent does not satisfy that requirement. As in any case involving statutory interpretation, we begin with the language of the statute itself. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). Section 112 provides, in relevant part, that:

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[4] Pfizer is supported by *amicus curiae* Eli Lilly & Co., which makes similar arguments.

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (2000). Three separate requirements are contained in that provision: (1) "the specification shall contain a written description of the invention"; (2) "[t]he specification shall contain a written description . . . of the manner and process of making and using it [*i.e.*, the invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same"; and (3) "[t]he specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."

In common parlance, as well as in our and our predecessor court's case law, those three requirements are referred to as the "written description requirement," the "enablement requirement," and the "best mode requirement," respectively. *See In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971) ("*Robert Moore*") ("This first paragraph analysis in itself contains several inquiries. Considering the language of the statute, it should be evident that these inquiries include determining whether the subject matter defined in the claims is described in the specification, whether the specification disclosure as a whole is such as to enable one skilled in the art to make and use the claimed invention, and whether the best mode contemplated by the inventor of carrying out that invention is set

forth."). The United States Supreme Court also recently acknowledged written description as a statutory requirement distinct not only from the best mode requirement, but also from enablement. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) ("[A] number of statutory requirements must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not obvious. 35 U.S.C. §§ 101-103 (1994 ed. and Supp. V). In addition, the patent application must *describe, enable, and set forth the best mode* of carrying out the invention. § 112 (1994 ed.). These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public." (emphasis added)).

Although there is often significant overlap between the three requirements, they are nonetheless independent of each other. *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). Thus, an invention may be described without an enabling disclosure of how to make and use it. A description of a chemical compound without a description of how to make and use it, unless within the skill of one of ordinary skill in the art, is an example. Moreover, an invention may be enabled even though it has not been described. *See, e.g., In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971) ("[I]t is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not describe that invention."). Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B *if* B were described. A specification can likewise describe an invention without enabling the practice of the full breadth of its claims. Finally, still further disclosure might be

necessary to satisfy the best mode requirement if otherwise only an inferior mode would be disclosed. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed. Cir. 1987).

The "written description" requirement serves a teaching function, as a "*quid pro quo*" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." *Enzo*, 323 F.3d at 970. Rochester argues, however, that this teaching, or "public notice," function,[5] although "virtually unchanged since the 1793 Patent Act," in fact "became redundant with the advent of claims in 1870." We disagree. Statutory language does not become redundant unless repealed by Congress, in which case it no longer exists.

In addition, and most significantly, our precedent clearly recognizes a separate written description requirement. In *In re Ruschig*, 379 F.2d 990 (CCPA 1967), our predecessor court affirmed a rejection under 35 U.S.C. § 112 of a claim that was added to a patent application during prosecution to provoke an interference. That application had originally included a claim directed to a genus of chemical compounds, all having a central benzenesulphonylurea structure and two variable substituents attached at

[5] We and the Supreme Court have frequently used the term "public notice" in connection with claims and discussion of the doctrine of equivalents, the point being that the public is entitled to notice of what the inventor has claimed and the Patent and Trademark Office has agreed should be the subject of a patent's limited right to exclude. However, while the role of the claims is to give public notice of the subject matter that is protected, the role of the specification is to teach, both what the invention is (written description) and how to make and use it (enablement).

specified sites on that structure. *Id.* at 994. As a result of the way in which those substituents were defined in the claim, the genus defined by the claim included thousands of compounds, corresponding to all the possible permutations of the substituents. *Id.* at 993-94. The added claim, in contrast, was directed to a single member of that genus, N-(p-chlorobenzenesulfonyl)-N-propylurea. *Id.* at 991. Although that compound was within the literal scope of the originally filed claim, it was never "named or otherwise exemplified" in the appellants' original patent application. *Id.* at 992. The examiner rejected the added claim on the basis that the specific compound was not adequately supported by the specification as filed. *Id.*

The Patent Office Board of Appeals, and subsequently the Court of Customs and Patent Appeals, affirmed that rejection. In reaching its decision, the court observed that the claimed compound was not described in the specification and would not "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound." *Id.* at 996. It did not teach the specific compound. Although the appellants had argued that the rejection was improper because one skilled in the art would be enabled by the specification to make the specific compound, the court explained that it was "doubt[ful] that the rejection [was] truly based on section 112, at least on the parts relied on by appellants [*i.e.*, the 'language therein about enabling one skilled in the art to make the invention']. If based on section 112, it is on the requirement thereof that 'The specification shall contain a written description of the invention.'" *Id.* at 995-96.

While it is true that this court and its predecessor have repeatedly held that claimed subject matter "need not be described in haec verba" in the specification to satisfy the written description requirement, *e.g., In re Smith,* 481 F.2d 910, 914 (CCPA 1973), it is also true that the requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." *Enzo,* 323 F.3d at 968. We have further explained that:

> [T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement . . . . A description of an anti-inflammatory steroid, *i.e.,* a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [*Regents of the Univ. of Cal. v.*] *Eli Lilly* [*& Co., Inc.*], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("*Lilly*")] . . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Id.*

Enzo, 323 F.3d at 968. Similarly, for example, in the nineteenth century, use of the word "automobile" would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels on axles, etc. Thus, generalized language may not suffice if it does not convey the detailed identity of an invention. In this case, there is no language here, generalized or otherwise, that describes compounds that achieve the claimed effect.

Rochester is also factually incorrect in its assertion that a written description requirement separate from the enablement requirement was not recognized prior to *Ruschig* in 1967. For example, in *Jepson v. Coleman,* 314 F.2d 533 (CCPA 1963), our predecessor court explicitly rejected the notion that an enabling disclosure necessarily satisfies the written description requirement: "It is not a question whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device." *Id.* at 536. Still earlier, that court affirmed a decision of the Board of Appeals of the Patent Office affirming the rejection of an applicant's claims on the basis that those claims were "broader than the disclosure in appellant's application and . . . were properly rejected for that reason." *In re Moore,* 155 F.2d 379, 382 (CCPA 1946) ("*Wm. Moore*"). The court stated that it "is well settled that claims in an application which are broader than the applicant's disclosure are not allowable." *Id.*

Similarly, in 1962 the court affirmed the Board's rejection of the original claims in a patent application, based on, *inter alia,* the rejected claims' "fail[ure] to meet the requirements of 35 U.S.C. § 112 in that they are broader than the invention described in the written description thereof as set forth in the specification." *In re Sus,* 306 F.2d 494, 497 (CCPA 1962). In that case, the court specifically identified the "pertinent portions of 35 U.S.C. § 112 to be here considered" as the following: "'The specification shall contain a written description of the invention * * * . The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his

invention.'" *Id.* at 494 n. 1 (ellipsis in original). According to the court, "one skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals would be suitable for such purposes." *Id.* at 504.[6] The issues in *Jepson, Wm. Moore*, and *Sus* were clearly not confined to a determination whether the enablement requirement was met. They were independent written description issues.

Rochester's suggestion in its brief that *Lilly* "compounded *Ruschig*'s error" by "invoking the written description requirement in a case without priority issues" is similarly deficient. Neither *Wm. Moore* nor *Sus*, for example, involved any priority issues. Moreover, even if the court had never had occasion to apply the written description requirement to original claims prior to the 1987 *Lilly* decision, that requirement was nonetheless always present. As explained in *Enzo*:

> It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time . . . .

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[6] In *Sus*, the claims at issue were rejected by the patent examiner under 35 U.S.C. § 112, ¶ 2. However, the Court of Customs and Patent Appeals pointed out in subsequent cases that that rejection was "more properly considered under the first paragraph of that section." *In re Robins*, 429 F.2d 452, 457 n. 8 (CCPA 1970).

> . . . As for the lack of earlier cases on this issue, it regularly happens in adjudication that issues do not arise until counsel raise them, and, when that occurs, courts are then required to decide them.

323 F.3d at 971-72 (Lourie, J., concurring in Denial of Petition for Rehearing En Banc). In any event, the basic requirement of a written description of an invention exists whether a question of priority has arisen or not. The statute does not limit the requirement to cases in which a priority question arises.

Indeed, as early as 1822 the Supreme Court recognized the existence of separate written description and enablement requirements:

> [T]he patent act requires . . . that the party [*i.e.*, the inventor] "shall deliver a written description of his invention, in such full, clear, and exact terms, as to distinguish the same from all other things before know[n], and to enable any person skilled in the art or science, &c. &c. to make, compound, and use the same." The specification, then has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34 (1822). The Patent Act of 1793, 1 Stat. 318, which was in force at the time *Evans* was decided, required, in relevant part, that every inventor "deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science . . . to make, compound, and use the same . . . ." *In re Barker,* 559 F.2d 588, 592 (CCPA 1977) (ellipses in original). Although the patent statutes have been extensively revised since 1822, most notably in the addition of the requirement of claims, the language of the present statute is not very different in its articulation of the written description requirement. *Id.* at 592-94.

Rochester also argues that *Fiers v. Revel,* 984 F.2d 1164 (Fed. Cir. 1993), *Lilly,* and *Enzo* are all distinguishable because they were limited to DNA-based inventions. Rochester asserts that undisputed evidence shows that, based on the '850 patent's teachings, skilled artisans would be able to recognize COX-2-selective inhibitors.

We agree with Rochester that *Fiers, Lilly,* and *Enzo* differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue; in fact, where there might be some basis for finding a written description requirement to be satisfied in a genetics case based on the complementariness of a nucleic acid and, for example, a protein, that correspondence might be less clear in a non-genetic situation. In *Enzo,* we explained that functional

descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are "coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." 323 F.3d at 964 (quoting from the PTO's *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement,* 66 Fed. Reg. 1099, 1106). DNA and RNA are each made up of just four building blocks that interact with each other in a highly predictable manner. Each of those building blocks, or "nucleotides," is characterized by a unique "base": In the case of DNA, the four nucleotides include the bases adenine, thymine, cytosine, and guanine; RNA also includes adenine, cytosine, and guanine, but contains the base uracil in place of thymine. Adenine on one strand of DNA binds, or "hybridizes," to thymine on the other; in RNA, adenine binds to uracil; and in either DNA or RNA, cytosine binds to guanine. Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a "complementary" strand that will bind to it. Therefore, disclosure of a DNA sequence might support a claim to the complementary molecules that can hybridize to it.

The same is not necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, let alone have been within the purview of one of ordinary skill in the art in the 1993-1995 period in which the applications that led to the '850 patent were filed.

Rochester and its experts do not offer any persuasive evidence to the contrary. As the district court pointed out:

> Tellingly, . . . what plaintiff's experts' [sic] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds – which, as the patent makes clear, are necessary to practice the claimed method – would be suitable, nor would one know how to find such a compound except through trial and error . . . . Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method – a compound that selectively inhibits PGHS-2 activity – was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Univ. of Rochester, 249 F. Supp. 2d at 229.

Rochester also attempts to distinguish *Fiers, Lilly*, and *Enzo* by suggesting that the holdings in those cases were limited to composition of matter claims, whereas the '850 patent is directed to a method. We agree with the district court that that is "a semantic distinction without a difference." *Univ. of Rochester,* 249 F. Supp. 2d at 228. Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively

inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment." *Id.*

We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure, but the application must nonetheless "describe the claimed subject matter in terms that establish that [the applicant] was in possession of the . . . claimed invention, including all of the elements and limitations." *Hyatt v. Boone,* 146 F.3d 1348, 1353 (Fed. Cir. 1998). *But see Enzo,* 323 F.3d at 969 ("Application of the written description requirement, however, is not subsumed by the 'possession' inquiry. A showing of 'possession' is ancillary to the *statutory* mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention."). The specification must teach the invention by describing it.

Rochester also contends that "[t]he patent-in-suit cannot be *per se* invalid," because written description is a question of fact. Rochester further argues that:

> [C]onsistent with written description's fact-intensive nature, this Court has recognized diverse forms of description, including description primarily (if not entirely) based on functional characteristics. In *Union Oil* [*Co. v. Atlantic Richfield Co.,* 208 F.3d 989 (Fed. Cir. 2000) ("*Unocal*")], for example, the Court rejected the argument that the patent-in-suit was invalid because it described claimed gasoline mixtures by their "desired characteristics," rather than by their "exact chemical component[s]."

In response, Pfizer argues that the district court did not apply a *per se* rule, and that written description of a method of selectively inhibiting the activity of an enzyme by administering a chemical compound is insufficient unless a skilled artisan can recognize the identity of the compound, and the description must convey what the compound is, not just what it does. Pfizer points out that the district court found that the '850 patent does not disclose the structure or physical properties of any of the compounds required to practice the claimed methods, and that the structure of such compounds cannot be deduced from any known structure-function correlation. Pfizer agrees with the district court that the '850 patent discloses nothing more than a hoped-for function for an as-yet-to-be-discovered compound, and a research plan for trying to find it.

We agree with Pfizer that the '850 patent is deficient in failing to adequately describe the claimed invention. First, although compliance with the written description requirement is a question of fact, *Vas-Cath,* 935 F.2d at 1116, Rochester's argument that a patent may not be held invalid on its face is contrary to our case law. In *PIN/NIP, Inc. v. Platte Chemical Co.,* 304 F.3d 1235 (Fed. Cir. 2002), for example, we held that a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met. Similarly, in *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.,* 264 F.3d 1111 (Fed. Cir. 2001), we held that "[n]o reasonable juror could find that [an appellant's] original disclosure was sufficiently detailed to enable one of skill in the art to

recognize that [the appellant] invented what is claimed," and accordingly upheld a grant of summary judgment. *Id.* at 1119.

Second, it is undisputed that the '850 patent does not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known. The '850 patent does contain substantial description of the cyclooxygenases, including the nucleotide sequences of coding and promoter regions of the genes that encode human COX-1 and COX-2 and a comparison of those sequences. *See, e.g.*, '850 patent, figs. 6A-6B, 10A-10D, and 11A-11C. The patent also describes in detail how to make cells that express either COX-1 or COX-2, but not both, *id.* § 5.2, at cols. 8-20, as well as "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product; and methods of treating diseases characterized by aberrant PGHS-2 activity using such compounds," *id.* at col. 8, ll. 2-7; *see also id.* § 5.6, at cols. 24-25. Such assay methods are in fact claimed in the '479 patent, *i.e.*, Rochester's *other* patent based on the same disclosure. The '850 patent specification also describes what can be done with any compounds that may potentially be identified through those assays, including formulation into pharmaceuticals, routes of administration, estimation of effective dosage, and suitable dosage forms. *Id.* § 5.8, at cols. 27-34. As pointed out by the district court, however, the '850 patent does not disclose just "*which* 'peptides, polynucleotides,

and small organic molecules' have the desired characteristic of selectively inhibiting PGHS-2." *Univ. of Rochester,* 249 F. Supp. 2d at 224. Without such disclosure, the claimed methods cannot be said to have been described. As we held in *Lilly,* "[a]n adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566 (quoting *Fiers,* 984 F.2d at 1171). For reasons stated above, that requirement applies just as well to non-DNA (or -RNA) chemical inventions.

Third, Rochester's reliance on *Unocal* is unavailing. Although we held in that case that a "descri[ption] of the exact chemical component of each combination that falls within the range claims of the . . . patent" is not necessary to comply with § 112, we explained that the patentee is nonetheless required to provide sufficient description to show one of skill in the art that the inventor possessed the claimed invention at the time of filing. *Unocal,* 208 F.3d at 997. Evidence was adduced in that case that artisans skilled in petroleum refining were aware of the properties of raw petroleum sources and knew how to mix streams of such sources to achieve a final product with desired characteristics. Accordingly, we held that the written description requirement was satisfied in that case by specifying the ranges of properties of the claimed gasolines, reflecting the way that oil refiners actually formulate gasoline, such that one skilled in the art could recognize what was being claimed. *Id.* at 992. The present case is not analogous. Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on its vague functional description as "a

non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product."[7]

Rochester also cites *In re Edwards,* 568 F.2d 1349 (CCPA 1978), and *In re Herschler,* 591 F.2d 693 (CCPA 1979), in support of its arguments. Those cases are also inapposite. In *Edwards,* the court held that the written description requirement was satisfied by a specification that described a claimed compound by the process by which it was made, rather than by its structure, because the court found that Edwards' application, "taken as a whole, reasonably leads persons skilled in the art to the [recited reactions] and, concomitantly, to the claimed compound." 568 F.2d at 1354. In marked contrast to the Edwards application, the specification of the '850 patent contains no disclosure of any method for making even a single "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product." In *Herschler,* the court found adequate written description support for broad claims to processes for topically administering a physiologically active steroidal agent to a human or animal by concurrently administering the steroidal agent and dimethyl sulfoxide ("DMSO"), even though the specification disclosed only one example of a "physiologically active steroidal agent." Critically, however, there was no question in that case that, unlike "non-steroidal compound[s] that

[7] Indeed, if compounds that selectively inhibit activity of the PGHS-2 gene product *had* been known in the art, it is difficult to see how the claims of the '850 patent would have satisfied the novelty requirement of 35 U.S.C. § 102. After all, the novelty of those claims, if any, would appear to reside in the fact that COX-2 selective inhibitors were previously unknown. The issue of patentability under § 102, however, was not decided by the district court, and we do not address it further.

selectively inhibit[] activity of the PGHS-2 gene product," numerous physiologically active steroidal agents were known to those of ordinary skill in the art. As the court there noted, "[w]ere this application drawn to novel 'steroidal agents,' a different question would be posed." 591 F.2d at 701. The novelty in that invention was the DMSO solvent, not the steroids.

Although cases such as *Unocal, Enzo, Edwards*, and *Herschler* demonstrate that patent applicants have some flexibility in the "mode selected for compliance" with the written description requirement, neither those cases nor any other cases cited by Rochester eliminate the requirement that the patent specification set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed. The only claims that appear to be supported by the specification are claims to assay methods, but those claims were already issued in the '479 patent.

Rochester argues that "[t]he appealed decision vitiates universities' ability to bring pioneering innovations to the public," and that:

> Congress has determined that licensing of academia's inventions to industry is the best way to bring groundbreaking inventions to the public. *See* 35 U.S.C. § 200. By vesting in universities the patent rights to their federally funded research, the Bayh-Dole Act of 1980 encouraged "private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application." H.R. Rep. No. 96-1307, pt. 1, at 3 (1980).

Further, *amici* the University of California and the University of Texas assert that "[t]his Court's decision will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector."

That argument is unsound. The Bayh-Dole Act was intended to enable universities to profit from their federally-funded research. It was not intended to relax the statutory requirements for patentability. As pointed out by *amicus* Eli Lilly, "no connection exists between the Bayh-Dole Act and the legal standards that courts employ to assess patentability. Furthermore, none of the eight policy objectives of the Bayh-Dole Act encourages or condones less stringent application of the patent laws to universities than to other entities. *See* 35 U.S.C. § 200."[8]

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[8] Section 200, entitled "Policy and objective," provides that:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

35 U.S.C. § 200 (2000).

In sum, because the '850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods – an essential element of every claim of that patent – and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art[9] at the relevant time, Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention. Accordingly, we affirm the district court's grant of Pfizer's motion for summary judgment.

In view of our affirmance of the district court's decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further.

With respect to the third asserted error, relating to the denial of Rochester's cross-motion for summary judgment, Rochester argues that because Pfizer adduced no evidence, other than the patent in suit, to support its written description defense, Rochester was entitled to summary judgment on that issue. Rochester contends that, because all issued patents are presumed to be valid, the district court was wrong to conclude that the '850 patent constitutes clear and convincing proof of its own invalidity.

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[9] In *O'Reilly v. Morse*, 56 U.S. 62 (1853), the Supreme Court stated "[Morse] claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of the opinion that the claim is too broad, and not warranted by law." *Id.* at 113. Likewise, Rochester has claimed a method that could not be adequately described at the time its application was filed. As we explained in *Fiers*, "one cannot describe what one has not conceived." 984 F.2d at 1171.

Pfizer responds by arguing that there is no issue of material fact in dispute and that the '850 patent is invalid as a matter of law. Pfizer argues further that the district court properly found that Rochester's experts' declarations did not raise any issue of material fact, because they focused only on the use and function of the screening assay, rather than on the disclosure in the specification of a suitable compound. According to Pfizer, common sense dictates that one has not described a method of treating a disease with a drug if he has not disclosed any such drug or even if one exists, and there is accordingly no need for any evidence of invalidity beyond the '850 patent itself.

Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit proves its own invalidity, *see, e.g., PIN/NIP,* 304 F.3d at 1235; *TurboCare,* 264 F.3d at 1111, and as detailed in section I above, we conclude that the '850 patent clearly and convincingly does just that. The patent's claims all require a COX-2 selective compound, but no COX-2 selective compound is disclosed in the patent, and it is undisputed that there was no pre-existing awareness in the art of any compound having COX-2 selective activity. Accordingly, we hold that the district court did not abuse its discretion by denying Rochester's cross-motion for summary judgment.[10]

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[10] Although we have treated the issue in this case as one of written description, as it was argued and decided below, underlying that question is the fundamental issue whether Rochester actually invented the subject matter it claimed in the '850 patent as required by 35 U.S.C. § 102(f). As the Supreme Court has cautioned, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson,* 383 U.S. 519, 536 (1966).

(Continued on following page)

CONCLUSION

Because the court did not err in holding the '850 patent to be invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment in favor of Pfizer on that ground, the decision of the district court is

AFFIRMED.

Here the patentee has done no more than invent a search method, *i.e.*, a method of identifying a selective COX-2 inhibitor, much less did it invent, as claimed in the '850 patent, a method of using any such compound to selectively inhibit COX-2 in humans. Under these circumstances, it might appear that the patentee also failed to satisfy the requirements of section 102(f).

APPENDIX B

UNIVERSITY OF ROCHESTER, a New York Education Corporation, Plaintiff, v. G.D. SEARLE & CO., INC., a Delaware Corporation, et al., Defendants.

00-CV-6161L

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NEW YORK

249 F. Supp. 2d 216; 2003 U.S. Dist. LEXIS 3030; 68 U.S.P.Q.2D (BNA) 1424

March 5, 2003, Decided

David M. Lascell, Harter, Secrest and Emery, LLP, Rochester, NY, Carol E. Heckman, Harter, Secrest & Emery, LLP, Buffalo, NY, Gerald P. Dodson, Eric S. Walters, Morrison & Foerster, LLP, Palo Alto, CA, Erica D. Wilson, Win Hwango, Steven J. Keoninger, Kenneth A. Kuwayti, Cynthia L. Lopez, Marc J. Pernick, Kanika Radhakrishnan, Jennifer L. Piel, Cathryn M. Sadler, Bryan Ward, Rachel Williams, Emily A. Evans, Erik Jeffrey Olson, Morrison & Foerster, LLP, Palo Alto, CA, Harold A. Jurland, Eric J. Wared, Ward, Norris, Heller & Reidy, LLP, Rochester, NY, for University of Rochester.

Michael Wolford, Wolford & LeClair, LLP, Rochester, NY, Henry J. Renk, Nicholas M. Cannella, Robert L. Baechtold, Fitzpatrick, Cella, Harper, Scinto, New York City, David T. Pritikin, Richard F. O'Malley, Charles W. Douglas, Sidley Austin Brown and Wood, Chicago, IL, for G.D. Searle, Inc., Monsanto Co., Pharmacia Corp.

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Becker, Kaye, Scholer, Fierman, Hays & Handler, LLP, Washington, DC, for Pfizer, Inc.

OPINION:

DECISION AND ORDER

LARIMER, District Judge

Patent law often involves subject matter and legal principles that can be both complex and arcane. But there are some basic principles that should be evident even to the lay person.

An "inventor" or patentee is entitled to a patent to protect his work but only if he produces or has possession of something truly new and novel. The "invention" he claims must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection.

The patent at issue here does not do that. What the reader learns from this patent is a wish or plan or first step for obtaining a desired result. What he appreciates is that the patentee had a goal for achieving a certain end result. The reader can certainly appreciate the goal but establishing goals does not a patent make. The reader also learns that the patentee had not proceeded to do what was necessary to accomplish the desired end. In my view, such an "invention" is not really one at all. As the Court of Appeals for the Federal Circuit stated in a case involving similar issues, an inadequate patent description that merely identifies a plan to accomplish an intended result

"is an attempt to preempt the future before it has arrived." *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir. 1993). Such a patent fails to comply with the requirements of the federal statutes concerning issuance of patents and, therefore, must be held invalid.

BACKGROUND

The patent at issue, United States Patent No. 6,048,850 ("the '850 patent") relates to a new generation of pain relief medication that does not produce certain undesirable side effects, particularly stomach irritation, associated with many other pain relievers such as aspirin, acetominophen, ibuprofen, etc. Specifically, the '850 patent claims a pharmaceutical "method for selectively inhibiting PGHS-2 activity in a human host" in which "the activity of PGHS-1 is not inhibited." '850 Patent, col. 71, lines 36-37, 43-44. PGHS-1 and PGHS-2[1] are two enzymes produced by the human body. They play a role in the manufacture of hormones known as prostaglandins.

Prostaglandins perform various functions; prostaglandins produced through the activity of PGHS-1, for example, are beneficial and help protect the stomach lining. PGHS-2, on the other hand, is associated with inflammatory stimuli. When those stimuli are present, production of PGHS-2 increases, which in turn leads to an increase in the prostaglandins produced through the activity of PGHS-2. Those prostaglandins, however, cause pain and inflammation.

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[1] PGHS-1 and PGHS-2 are also sometimes referred to as Cox-1 and Cox-2. These terms are taken from the chemical names prostaglandin H synthase and cyclooxygenase.

For many years, it was not known that in mammals, there are these two cyclooxygenase enzymes, *i.e.,* PGHS-1 and PGHS-2. Many pain relievers that were employed prior to the discovery that there were two such enzymes used non-steroidal anti-inflammatory drugs ("NSAIDs"), which inhibited the activity of both PGHS-1 and PGHS-2. This resulted in relief from the pain and inflammation associated with PGHS-2, but also caused stomach upset and irritation because of the lowered levels of PGHS-1.

The claimed invention here arises out of the discovery in the early 1990s by scientists at the University of Rochester of the existence of PGHS-2, and its separate functions from those performed by PGHS-1. The inventors theorized that if a method were found of targeting PGHS-2 alone, without affecting PGHS-1 activity, it would be possible to provide relief from pain and inflammation without the gastrointestinal side effects associated with most NSAIDs. In other words, the goal was to reduce PGHS-2 activity, which causes pain and inflamation, without adversely affecting PGHS-1 activity, which is beneficial because, in part, it acts to reduce stomach irritation.

To that end, the scientists developed an assay for determining whether a particular non-steroidal compound is suitable for use in practicing the claimed invention. That assay, which is described in § 5.6 and in claim 6 of the patent, involves contacting genetically engineered cells containing either PGHS-1 or PGHS-2, but not both, with the compound being tested, exposing the cell and compound to a predetermined amount of arachidonic acid (which is capable of being transformed into a prostaglandin) for thirty minutes, and then determining the extent to which the acid in each cell has been converted

into prostaglandin, compared to the amount transformed in control cells that were not exposed to the compound. As stated by plaintiff's counsel at oral argument, this assay essentially involves "run[ning a compound] through the assay to figure out which compound hybridizes to cyclooxygenase-2 and prevents its activity, but don't [sic] affect the activity of cyclooxygenase-1." Transcript, July 25, 2002 (Docket # 247) at 18, lines 13-16. In other words, the compound is simply tested to see whether or not it performs in the manner called for by the method described in the '850 patent.

On April 11, 2000 – the same day that the '850 patent was issued – the University of Rochester brought this patent infringement action against defendants G.D. Searle & Co., Inc. ("Searle"), Pfizer, Inc., Monsanto Co., and Pharmacia Corp., seeking injunctive relief and damages for alleged infringement of the '850 patent. Defendants have moved for summary judgment of patent invalidity on the ground that the '850 patent does not comply with the written-description requirement of 35 U.S.C.§ 112, ¶ 1. Defendants base this assertion on the fact that while the patent calls for use of a "compound" that selectively inhibits PGHS-2 activity, the patent specification does not identify any such compound. Plaintiff has cross-moved for summary judgment on the same issue, seeking an order finding that the '850 patent is not invalid for failure to meet the written-description requirement.

Defendants have also moved for summary judgment of patent invalidity for non-enablement, arguing that the '850 patent fails to describe the invention in terms sufficient "to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" the invention. 35 U.S.C.§ 112.

DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed.R.Civ.P. 56(c). A genuine issue exists if the evidence is such that a reasonable factfinder could find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.,* 103 F.3d 978, 980 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Anderson,* 477 U.S. at 248, 106 S.Ct. 2505; *General Mills,* 103 F.3d at 980.

"When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *Eli Lilly and Co. v. Barr Labs., Inc.,* 251 F.3d 955, 962 (Fed. Cir. 2001) (citing *Anderson,* 477 U.S. at 252-53, 106 S.Ct. 2505), *cert. denied,* 534 U.S. 1109, 122 S.Ct. 913 (2002). In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor. *Anderson*; 477 U.S. at 255, 106 S.Ct. 2505; *Transmatic, Inc. v. Gulton Indus., Inc.,* 53 F.3d 1270, 1274 (Fed. Cir. 1995).

Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through clear and convincing evidence, *see Al-Site Corp. v. VSI Int'l, Inc.,* 174 F.3d 1308, 1323 (Fed. Cir. 1999); *Monarch Knitting Mach. Corp. v. Sulzer Morat*

GmbH, 139 F.3d 877, 881 (Fed. Cir. 1998); *United States Surgical Corp. v. Ethicon, Inc.,* 103 F.3d 1554, 1563 (Fed. Cir.), *cert. denied,* 522 U.S. 950, 118 S.Ct. 369, 139 L.Ed.2d 287 (1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable finder of fact could invalidate the patent. *Eli Lilly,* 251 F.3d at 962.

II. Written-Description Requirement

A. General Standards

Defendants assert that the '850 patent is invalid for failure to comply with the written-description requirement. That requirement is contained in 35 U.S.C. § 112, ¶ 1, which provides that

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

Whether a specification complies with the written-description requirement is a question of fact. *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1563 (Fed. Cir. 1991); *Ralston Purina Co. v. Far-Mar-Co, Inc.,* 772 F.2d 1570, 1575 (Fed. Cir. 1985). As in other areas of the law, however, if the

court finds that there is no genuine issue of material fact as to this issue, summary judgment is appropriate. *See, e.g., TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1120 (Fed. Cir. 2001) (affirming summary judgment of invalidity for failure to meet written-description requirement).

In the case at bar, both sides have moved for summary judgment on the written-description issue and, therefore, neither believes that there are fact issues. While that fact does not necessarily mean that either of them is entitled to summary judgment, *see, e.g., BBS Power Mod, Inc. v. Prestolite Elec., Inc.*, 71 F.Supp.2d 194, 202 (W.D.N.Y.1999) (denying cross-motions for summary judgment on ground that genuine issues of material fact existed), it does suggest that there are no issues of fact here, and I find that there are none.

Although compliance with § 112, ¶ 1 is a factual issue that must be determined on a case-by-case basis, the real issue here is simply whether a written description of a claimed method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial-and-error process.[2]

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[2] Plaintiff also contends that the Court must first construe the claims of the '850 patent before deciding the written-description issue. Although the Federal Circuit has stated that "[t]he first step in any invalidity analysis is claim construction . . . ," *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000), a court need not decide the meaning of all disputed claims if the construction of the claims would have no bearing on the invalidity analysis. *See, e.g., id.* (finding it unnecessary to decide whether district court correctly

(Continued on following page)

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath,* 935 F.2d at 1563; *see also Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli,* 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572.

B. Biotechnology Patents – Defining a Substance by its Function

The Court of Appeals for the Federal Circuit has on more than one occasion discussed the written-description requirement as it applies to biotechnology patents, particularly those in which a substance is defined only by a

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construed the term "cell," since claim in question was obvious in any event). In the instant case, plaintiff has advanced no construction of any of the claims of the '850 patent that would bear upon the written-description issue, or that would affect my decision on that issue. In particular, regardless of whether the Court adopts plaintiff's proffered construction of the claims, the '850 patent still requires the use of a "compound" that is defined in terms of its ability to selectively inhibit the activity of PGHS-2 and not that of PGHS-1.

description of its function or the desired result of its use. For example, in *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied,* 523 U.S. 1089, 118 S.Ct. 1548 (1998), the court affirmed a district court ruling that all of the claims of a patent were invalid because the specification did not provide an adequate written description of the rat DNA that was required by the asserted claims. The court said that "[a]n adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly,* 119 F.3d at 1566 (quoting *Fiers,* 984 F.2d at 1171).

Likewise, in *Fiers,* the court held (in the context of an interference proceeding) that a patent application failed to satisfy the written-description requirement where the claimed invention called for a "DNA which codes for a human fibroblast interferon-beta polypeptide" ("ß-IF"), and the application disclosed a method for isolating a fragment of the DNA coding for ß-IF as well as a method for isolating messenger RNA coding for ß-IF, but did not disclose a complete DNA sequence coding for ß-IF. In reaching that holding, the court stated that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." 984 F.2d at 1170. The court stated that the disclosure contained in the application "just represents a wish, or arguably a plan, for obtaining the DNA," and that "it does not indicate that [the applicant] was in possession of the DNA." *Id.* at 1171. The court added that a description of DNA requires "a precise

definition, such as by structure, formula, chemical name, or physical properties . . . ." As referenced above, the court said that "[c]laiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." *Id.*

The Federal Circuit recently revisited this area in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002). The patent in that action was directed to a "nucleic acid probe" that would selectively hybridize, or bind, to the genetic material of the bacteria that cause gonorrhea. The patentee derived three biochemical sequences that were able to achieve the desired result, which the patentee deposited in the form of a DNA molecule within an E. coli bacterial host at the American Type Culture Collection.

The patentee sued two of its competitors for infringement, and the defendants moved for summary judgment on the ground that the claims were invalid for failure to meet the written-description requirement. The district court granted the motion, concluding that the claimed composition of matter was defined only by its biological activity or function, which it held was insufficient to satisfy § 112, ¶ 1.

The Federal Circuit initially affirmed, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002), but on rehearing, the court determined that its initial ruling that a deposit may not satisfy the written-description requirement was incorrect. The court therefore vacated its prior decision and reversed summary judgment, finding that genuine issues of material fact existed regarding

satisfaction of the written-description requirement. 296 F.3d 1316.

In so holding, however, the court did not overturn its prior case law that "a mere wish or plan" for obtaining an invention is not enough to comply with § 112, ¶ 1. *Id.* at 1324 (quoting *Eli Lilly,* 119 F.3d at 1566). While the court did state that "[i]t is not correct . . . that all functional descriptions of genetic material fail to meet the written description requirement," *id.,* the court did *not* hold that all such functional descriptions *are* sufficient. Rather, the court adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed.Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia,* "functional characteristics *when coupled with a known or disclosed correlation between function and structure . . . .*" *Enzo,* 296 F.3d at 1324-25 (quoting Guidelines, 66 Fed.Reg. at 1106 (emphasis added)). Applying that standard, the court held that "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Id.* at 1325.

As to the patent before it, the court, noting that the claims were not limited to the deposited sequences, but were also directed to subsequences of the deposited sequences and mutated variations thereof, the number of which might have been "astronomical," *id.* at 1326, held

that there was an issue of fact as to whether the reference in the patent to the deposited sequences would describe those subsequences and variations to one of skill in the art sufficiently to demonstrate possession of the generic scope of the claims. *Id.* at 1327.[3]

Notably, however, the court rejected the plaintiff's argument that the written-description requirement for the generic claims was necessarily met as a matter of law because the claim language appeared *in ipsis verbis* in the specification. Stating that "[e]ven if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed," *id.* at 1328, the court stated, as an example, that a

> description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. Similarly, the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity. *A description of what a material does, rather than of what it is, usually does not suffice.*

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[3] The court also held that the patentee had raised a genuine issue of material fact as to whether a reasonable factfinder could conclude that the claimed sequences were described by their ability to hybridize to certain strains of gonorrhea bacteria whose genomic DNA, while not explicitly sequenced in the patent, was accessible to the public, since those bacteria had also been deposited. The court held that "[s]uch hybridization to disclosed organisms may meet the PTO's Guidelines stating that functional claiming is permissible when the claimed material hybridizes to a disclosed substrate." *Id.* at 1328.

Id. at 1329 (citing *Eli Lilly,* 119 F.3d at 1568) (emphasis added).

C. Written-Description Requirement as Applied to the '850 Patent

Applying these principles to the case at bar, I conclude that, as a matter of law, the '850 patent does not comply with the written-description requirement of § 112, and that defendants are therefore entitled to summary judgment on that issue. The patent does no more than describe the desired function of the compound called for, and it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work.

The specification states that the invention comprises, *inter alia,* "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product; and methods of treating diseases characterized by aberrant PGHS-2 activity using such compounds." '850 Patent, col. 8, lines 2-7. Nowhere, however, does it specify *which* "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.[4]

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[4] The patent does state that one compound, NS-398, is a "specific inhibitor of PGHS-2," '850 Patent col. 28 line 40. The inventors testified that they do not know if NS-398 can in fact be used in the claimed treatment method, however. *See* Deposition of Donald A. Young (Docket # 172, Ex. B), at 140; Deposition of Michael K. O'Banion (Docket # 172,

(Continued on following page)

Likewise, § 5.6 of the patent describes in detail the screening assay, "which will be useful for the development of drugs that selectively inhibit inflammation without producing the side effects due to inhibition of constitutive [*i.e.*, PGHS-1] prostaglandin production," but it does not identify any particular drugs that the assay will identify as suitable for this purpose. '850 Patent, col. 24, lines 34-37.

Ex. C), at 183-88. In response to defendants' request to admit that NS-398 is "a steroidal compound that selectively inhibits activity of the PGHS-2 gene product" as that expression is used in claim 1 of the '850 patent, plaintiff responded, in part, that it "cannot admit or deny the truthfulness of the statement . . . without surveying an entire body of scientific work concerning the chemical 'NS-398'" and arranging for expert review of that body of work. Docket # 172, Ex. D, at 16.

Defendants also allege that NS-398 was publicly described as an anti-inflammatory agent for use in humans more than a year before the earliest application for the '850 patent was filed. *See* European Patent Application No. 88310899.5 (pub. May 24, 1989) (Docket # 172, Ex. E). Defendants contend that if the '850 patent method claims covered the administration of NS-398 to a human, the claims would be invalid as anticipated under 35 U.S.C. § 102(b). *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001) ("it is axiomatic that that which would literally infringe if later anticipates if earlier"); *EMI Group North America Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349 (Fed. Cir. 2001) ("the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer") (quoting *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999)).

Although plaintiff states that it disputes defendants' assertion that NS-398 was so published in the prior art, Plaintiff's Statement of Undisputed Facts (Docket # 208) ¶ 10, it does so on the ground that plaintiff "does not understand" this assertion, and it offers no evidence to the contrary. *Id.* At any rate, plaintiff does not appear to argue that the patent's reference to NS-398 suffices to meet the requirements of § 112, ¶ 1.

Section 5.7, captioned "compounds identified in the screens," which might be expected to state which compounds had been identified by the inventors, instead states simply that "[t]he compounds identified in the screen will demonstrate the ability to selectively modulate the expression of PGHS-2. These compounds include but are not limited to nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof, as well as antisense, ribozyme, triple helix, antibody, and polypeptide molecules and small inorganic molecules." '850 Patent, col. 27, lines 29-35. There is no indication that the inventors themselves had identified any such compounds from among those listed, however.

The claims themselves add no further specificity, stating only that the patent claims, *inter alia,* a method "comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment . . . in which the compound inhibits the enzymatic activity of the PGHS-2 gene product, and has minimal effect on enzymatic activity of PGHS-1." '850 Patent, col. 71, lines 36-42.

In none of these descriptions, then, is there even any suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention. Instead, these purported descriptions of the needed compound are, insofar as their sufficiency for purposes of the written-description requirement is concerned, virtually indistinguishable from the *Enzo* court's example of a description of an anti-inflammatory steroid couched "in terms of its function of lessening inflammation of tissues," which, the court stated, "fails to distinguish any steroid from others having the same

activity or function," and which therefore fails to satisfy the written-description requirement.

I am not persuaded by plaintiff's contention that the holdings of *Enzo, Lilly*, and *Fiers* are limited to claims directed to DNA or nucleic acid sequences. That assertion is simply not supported by the language of the cases themselves. In *Fiers,* for instance, the Court of Appeals stated that "conception of a DNA, like conception of *any chemical substance,* requires a definition of that substance other than by its functional utility," 984 F.2d at 1169. Although the court there was discussing conception rather than written description, the court also stated that "[i]f a *conception* of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a *description* also requires that degree of specificity," since "one cannot describe what one has not conceived." *Id.* at 1171 (emphasis added).

In *Eli Lilly,* the court did draw a distinction between genetic material and other chemicals, stating that generic descriptions, which may be sufficient in claims involving other types of chemical materials, will often not suffice in claims to genetic material. The court said that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus,

> visualize or recognize the identity of the members of the genus.

119 F.3d at 1568.

In drawing this distinction, however, the court also stated that "[i]n claims involving [non-genetic] chemical materials, generic formulae *usually indicate with specificity what the generic claims encompass.* One skilled in the art can distinguish such a formula from others and *can identify many of the species* that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." *Id.* (emphasis added). There is no such specificity here, nor could one skilled in the art identify any particular compound encompassed by the claims. To the contrary, the specification states that suitable compounds *might* be found from among an array of organic and inorganic materials.

The *Lilly* court also stated that "[t]he description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention." *Id.* This statement was not qualified by reference to genetic material, and the case cited by the court in support of that statement, *In re Wilder,* 736 F.2d 1516 (Fed. Cir. 1984), *cert. denied,* 469 U.S. 1209, 105 S.Ct. 1173, 84 L.Ed.2d 323 (1985), did not involve any chemical-related claims, but claims directed to a mechanism for indicating the location of information recorded on a dictating machine. The *Wilder* court affirmed the PTO's rejection of those claims because the specification did "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate." *Id.* at 1521.

The *Enzo* court likewise did not indicate that its holding was limited to claims involving DNA. It is noteworthy that neither of the examples given by the court of insufficient descriptions were descriptions of genetic material, but of "an anti-inflammatory steroid" and "an antibiotic penicillin."[5]

Furthermore, to the extent that the *Enzo* court held that a functional description can meet the written-description requirement, it did so in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when *coupled* with a known or disclosed correlation between function and structure . . . ." No such correlation has been disclosed here.

Consistent with that standard, the central holding of *Enzo* was that with respect to "biological materials," *id.* at 1325, (a term which presumably encompasses more than simply genetic material), "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Id.* In other words, it is not necessary to give a precise chemical formula or description of a chemical structure when persons of ordinary skill in the art can ascertain what substance is being

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[5] I also note that the '850 patent itself purports to encompass nucleic acid; it states that among the compounds that might be identified through the claimed assay are "nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof . . . . " '850 Patent, col. 27, lines 31-35.

described by resort to the public depository where a specimen of that substance is kept. In the case at bar, however, no such deposit has been made.

Plaintiff has cited several cases decided by the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals, for the proposition that various types of descriptions, which do not necessarily include precise chemical formulas, can suffice to meet the written-description requirement with respect to chemical compounds. In finding that the '850 patent is deficient in that regard, however, I do not hold that it is a *sine qua non* that the patent set forth the exact chemical structure of the compounds in question. It is only necessary that the patent set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed. This the '850 patent fails to do.

The cases cited by plaintiff are not to the contrary. *Union Oil Co. v. Atlantic Richfield Co.,* 208 F.3d 989 (Fed. Cir. 2000), *cert. denied,* 531 U.S. 1183, 121 S.Ct. 1167, 148 L.Ed.2d 1025 (2001), for example, involved a patent claiming automotive gasoline compositions that reduced tailpipe emissions. Although "the claims d[id] not describe each gasoline product in terms of molecular structures or lists of ingredients," but rather "specif[ied] the chemical properties of the gasolines," this description "reflect[ed] the way oil refiners formulate gasoline," so that "the claims which define[d] the invention in terms of various characteristics also inform[ed] those of skill in the art of the composition of the claimed gasoline fuels." *Id.* at 992.

Union Oil and the other cases relied upon by plaintiff, such as *In re Herschler,* 591 F.2d 693 (C.C.P.A.1979), and

In re Edwards, 568 F.2d 1349 (C.C.P.A.1978), indicate, as this Court has recognized, that it is not always necessary to set forth exact chemical formulas to satisfy § 112, ¶ 1, but they do not hold that a functional description of a chemical compound is necessarily sufficient. Rather, these cases simply reflect the fact that "[c]ompliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo,* 296 F.3d at 1324 (quoting *Vas-Cath,* 935 F.2d at 1563). In all of those cases, however, the description was found to contain enough information to lead a person skilled in the art to the claimed compound. *See Herschler,* 591 F.2d at 701 (finding that "the array of information supplied by appellant in the great-grandparent application [would] teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process"); *Edwards,* 568 F.2d at 1352, 1354 (application which described claimed compound by the process of making it contained adequate description, since "[i]t [wa]s undisputed that the . . . reactions [set forth in the application] will inherently produce, as the predominant component, the claimed compound"; the "application, taken as a whole, reasonably leads persons skilled in the art . . . to the claimed compound"). The '850 patent is completely lacking in that respect.

Plaintiff also argues that the requirements for written descriptions of claims to chemical compounds are irrelevant to this case because the '850 patent does not claim a compound, but a method of treatment by targeting PGHS-2 activity over PGHS-1 activity. Virtually any compound claim could be transformed into a method claim, however, simply by means of wording the claim in terms of a method of using the compound. With respect to the issue

before the Court, then, this is little more than a semantic distinction without a difference. The claimed method *depends* upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, as defendants argue, akin to "inventing" a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone. Without possession of such a substance, such a "cure" is illusory, and there is no meaningful possession of the method.

I recognize that the inventors and the research teams of which they were a part did apparently make some significant discoveries in this field. They realized, in light of the discovery of PGHS-2, that it would be quite beneficial if one could find a compound that would specifically target the activity of PGHS-2, but not that of PGHS-1.

What the inventors did *not* do, however, is succeed in taking the last, critical step of actually isolating such a compound, or at least of developing a process through which one skilled in the art would be directly led to such a compound. Absent that step, their discoveries, valuable though they might have been, did not blossom into a full-fledged, complete invention. Scientific discoveries, and theories based on those discoveries, frequently lay the groundwork for later inventions, but that does not make the discoverer the inventor as well.

In reaching this conclusion, the Court has also reviewed the declarations of plaintiff's two experts, Drs.

Edward Dennis, who holds a Ph.D. in Chemistry, and John McGiff, M.D., a pharmacology professor at New York Medical College in Valhalla, New York. They both opine that the first application in the series of applications leading to issuance of the '850 patent ("the '780 application") "reasonably conveys to the ordinary skilled team of workers that the University [of Rochester] inventors were in possession of the inventions claimed in the '850 patent as of September 22, 1992," *i.e.* the date the application was filed. McGiff. Decl. ¶ 10; Dennis Decl. ¶ 32.[6]

Dennis and McGiff agree that "[t]he '850 patent does not contain claims to any compounds, but rather claims their use in this novel method of treatment." Dennis Decl. ¶ 12; McGiff Decl. ¶ 5. They state that "it would not be necessary for one of ordinary skill in the art to know the structure of a compound before screening it to determine whether it was suitable for use in the claimed method." According to them, "one of ordinary skill in the art would expect that compounds suitable for use in the claimed methods could be identified using known non-steroid anti-inflammatory compounds as a starting point in the screening process." Dennis Decl. ¶ 13; McGiff Decl. ¶ 6.

What this amounts to, though, is once again simply trial and error. Knowing the "starting point" is not enough; that is little more than a research plan. The patent describes how to test compounds to determine whether they work, but it does not set forth any procedure that will necessarily lead to discovery of such a compound, nor does

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[6] Dennis and McGiff agree that "one" of ordinary skill in the art to which the '850 patent pertains is a team of scientists, with skills in medicinal chemistry, molecular biology, biochemistry, and pharmacology. Dennis Decl.¶ 15; McGiff Decl.¶ 7.

it even identify any particular class of compounds that contains at least one suitable member. *Cf. Herschler,* 591 F.2d at 701 (finding that "the array of information supplied by appellant . . . [would] teach one having ordinary skill in this art that one of the class of steroids *will operate* in the claimed process") (emphasis added); *Edwards,* 568 F.2d at 1354 (description of process for making claimed compound was adequate, since described process "will inherently produce . . . the claimed compound").[7]

Tellingly, then, what plaintiff's experts' do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds – which, as the patent makes clear, are necessary to practice the claimed method – would be suitable, nor would one know how to find such a compound except through trial and error, which hardly suggests conception of a complete invention. Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of that method – a compound that selectively inhibits PGHS-2 activity – was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

At one level, certainly, the claimed method is easy enough to understand. One simply administers a "compound" that inhibits the activity of PGHS-2 but not that of PGHS-1. Section 112, ¶ 1, however, requires the patentee

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[7] I recognize that *Edwards* involved a claim to a compound, whereas the '850 patent claims a method. The point is that the process described in the '850 patent will not "inherently produce" or lead to performance of the claimed method, since the method cannot be performed without a suitable compound.

to "show that an invention is *complete* by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was *in possession* of the claimed invention . . . ." Guidelines, 66 F.R. at 1106 (emphasis added); *see also New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002) ("the disclosure must show [that the inventor] had invented *each feature* that is included as a claim limitation") (emphasis added). Even if the inventors were reasonably certain that the necessary compound existed and could eventually be found, there is no showing in the patent that they knew that to be a fact. In short, without possession, or at least knowledge, of such a compound, or of a method certain to yield such a compound, the inventors could not have possessed the claimed invention, *i.e.*, a method of treatment using the compound. *See Vas-Cath*, 935 F.2d 1555, 1563-64 ("the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention"); *see also New Railhead Mfg.*, 298 F.3d at 1295 ("the [written description] requirement is not satisfied if one of ordinary skill in the art must first make the patented invention before he can ascertain the claimed features of that invention").

In effect, then, the '850 patent claims a method that cannot be practiced until one discovers a compound that was not in the possession of, or known to, the inventors themselves. Putting the claimed method into practice awaited someone actually discovering a necessary component of the invention. In some ways, this is reminiscent of the search for the so-called "philosopher's stone," eagerly sought after by medieval alchemists, which supposedly would transmute lead into gold. While the Court does not

mean to suggest that the inventors' significant work in this field is on a par with alchemy, the fact remains that without the compound called for in the patent, the inventors could no more be said to have possessed the *complete* invention claimed by the '850 patent than the alchemists possessed a method of turning base metals into gold.[8]

The Federal Circuit in *Fiers* made the following observation about "[t]he difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function":

> would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans. While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity.

Fiers, 984 F.2d at 1169. That concern is well illustrated by the case at bar.

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[8] A patent for the philosopher's stone was actually issued during the reign of Edward III. "The invention we now regard as a superstition, but the application was referred by the King to a commission, which reported favorably upon it, and the patent issued apparently upon what we now regard as sound doctrine, that the invention was new and useful." *McKeever v. United States,* 14 Ct.Cl. 396 (1878). It is not apparent whether the patentee claimed actually to possess the stone, or whether he simply described it in terms of its function, in the hope that he would be entitled to royalties should it ever be discovered.

III. Enablement Requirement

A. General Standards

Section 112 provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . ." This requirement "demands that the patent specification enable 'those skilled in the art to make and use the full scope of the claimed invention without undue experimentation.'" *National Recovery Technologies, Inc. v. Magnetic Separation Sys., Inc.,* 166 F.3d 1190, 1195 (Fed. Cir. 1999) (quoting *Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1365 (Fed. Cir.), *cert. denied,* 522 U.S. 963, 118 S.Ct. 397, 139 L.Ed.2d 310 (1997)) (internal quote omitted).

Whether a patent complies with the enablement requirement is a question of law, *Union Pacific Resources Co. v. Chesapeake Energy Corp.,* 236 F.3d 684, 690 (Fed. Cir. 2001); *Moleculon Research Corp. v. CBS, Inc.,* 793 F.2d 1261, 1268 (Fed. Cir. 1986), *cert. denied,* 479 U.S. 1030, 107 S.Ct. 875, 93 L.Ed.2d 829 (1987), although "the ultimate legal conclusion of enablement rests on factual underpinnings." *Union Pacific Resources,* 236 F.3d at 690. Enablement is determined as of the effective filing date of the patent, *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.,* 315 F.3d 1335, 1339 (Fed. Cir. 2003) (citing *In re Hogan,* 559 F.2d 595, 604 (C.C.P.A.1977)). As with the written-description requirement, the burden of showing invalidity due to nonenablement is on the party asserting the defense. *See, e.g., Morton, Int'l, Inc. v. Cardinal Chem. Co.,* 5 F.3d 1464, 1470 (Fed. Cir. 1993).

Particularly disputed here is whether the '850 patent requires "undue experimentation" before the claimed invention can be practiced by those skilled in the art. "To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech,* 108 F.3d at 1365 (quoting *In re Wright,* 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that

> [t]he test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.

PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (quotation and citation omitted); *see also In re Wands,* 858 F.2d 731, 736-40 (Fed. Cir. 1988) ("The key word is 'undue,' not 'experimentation'") (quoting *In re Angstadt,* 537 F.2d 498, 504 (C.C.P.A.1976)).

The factors that may be considered in determining whether a disclosure would require undue experimentation include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the

art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Wands, 858 F.2d at 737. "[A]ll of the [*Wands*] factors need not be reviewed when determining whether a disclosure is enabling." *Enzo Biochem, Inc. v. Calgene, Inc.* ("*Calgene*"), 188 F.3d 1362, 1371 (Fed. Cir. 1999); *see Amgen, Inc. v. Chugai Pharm. Co., Ltd.,* 927 F.2d 1200, 1213 (Fed. Cir.) (noting that these factors "are illustrative, not mandatory. What is relevant depends on the facts"), *cert. denied,* 502 U.S. 856, 112 S.Ct. 169, 116 L.Ed.2d 132 (1991).

B. Enablement Requirement as Applied to the '850 Patent

Although determination of the issue of enablement can rest upon "factual underpinnings," *Union Pacific Resources,* 236 F.3d at 690, I find that there are no factual issues here, and that this issue may properly be determined on summary judgment.[9] As with the written-description

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[9] It is unclear whether plaintiff contends that there are any issues of material fact here. At page 6 of its memorandum of law on enablement, plaintiff itself argues that it need not demonstrate the existence of any issues of fact here because, in plaintiff's view, defendants have not adduced any evidence of nonenablement (an assertion with which I disagree, as explained below). That memorandum and plaintiff's other submissions also concentrate on trying to show why the '850 patent is enabling, rather than on showing that there are facts in dispute.

In the conclusion of its brief, however, plaintiff states that although it has "amply demonstrated that the enablement requirement is satisfied here," and though defendants "have adduced *no evidence* supporting a finding of nonenablement," plaintiff "has assumed, for purposes of this Opposition only, that Defendants will contend that there is a genuine issue regarding all the facts recited" in plaintiff's Rule 56 statement. Therefore, plaintiff states, even if the Court finds that defendants have met their initial burden under Rule 56, "the

(Continued on following page)

requirement, I also conclude that the '850 patent does not comply with the enablement requirement of § 112. To practice the invention claimed in the patent, a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

As already stated, the '850 patent essentially calls for the use of trial and error to attempt to find a compound that will selectively inhibit PGHS-2 activity in a human host, which is the method claimed by the patent. The fact that it does so does not *per se* mean that the patent fails to meet the enablement requirement. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983) (district court erred in invalidating patents for indefiniteness because of its view that some "trial and error" would be needed, since "[t]here was no evidence and the [district] court made no finding that undue experimentation was required" to practice the invention), *cert. denied,* 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984).

It must be remembered, however, that "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas

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motion should be denied because there are many genuine issues of material fact."

As stated, it is difficult to tell from this whether plaintiff is asserting that there are issues of fact here or not. Even if the parties do dispute any facts, however, those facts are not material. For one thing, many of the "disputes" referenced in plaintiff's Rule 56 statement amount to little more than matters of semantics, *e.g.*, the meaning of "non-steroidal," or the parties' characterizations of, or arguments from, undisputed facts, *e.g.* whether the '850 patent "identifies" or "describes" suitable compounds. In addition, none of the facts or assertions set forth in plaintiff's Rule 56 statement would alter my conclusions of law set forth in this Decision and Order, even if I were to draw every reasonable inference relating to those facts in plaintiff's favor.

that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech,* 108 F.3d at 1366 (quoting *Brenner v. Manson,* 383 U.S. 519, 536, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion")). Thus, while the need for some experimentation is by no means necessarily fatal, "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Id.*

Such detail is lacking here. The patent does describe how to conduct assays "for the screening of drug actions on both" PGHS-1 and PGHS-2, '850 Patent, col. 24, lines 33-34. The patent states that the claimed "invention . . . provides a method to evaluate the relative inhibitory activity of a compound to selectively inhibit PGHS-2 versus PGHS-1 . . . ," and then goes on to describe the assay procedure. '850 Patent, col. 24, lines 60-62.

The patent also describes what to do with "[a]ny of the identified compounds" once they *have* been identified as selective PGHS-2 inhibitors. '850 Patent, col. 27, line 39. It discusses, for example, routes of administration to a host, determining an effective dose, and methods of manufacturing pharmaceutical compositions containing the compound.[10]

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[10] Defendants also assert that the '850 patent fails to enable the claimed method of treating humans because it does not sufficiently disclose specific dosages, formulations, or routes of administration. Because I find the patent invalid on the grounds set forth here, I need not reach that argument.

By its own terms, then, the '850 patent describes methods for "screening" and "evaluat[ing]" the effect of various compounds on PGHS-1 and -2 activity. It also describes some of the steps to be taken once a suitable compound has been identified, in order to make it possible to practice the claimed invention.

What the '850 patent does *not* do, however, is provide the necessary link between those two steps: actually finding a compound that works. It provides precious little guidance in the way of selecting a particular compound, or even of narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation.

Plaintiff contends that it need not have provided additional detail in this regard, because the procedures for finding the sought-after compound were well known in the art. One of plaintiff's experts, Dr. Mark J. Suto, who holds a Ph.D. in Medicinal Chemistry, states in his declaration (Docket # 329) that it is his "considered opinion that, as of September 1992, persons of ordinary skill in the relevant art could have practiced the methods of claims 1-7 of the '850 patent without undue experimentation, based on the disclosure of the September 1992 application and what was well known in the art." Suto Decl. ¶ 14. Dr. Suto states that in September 1992, the use of *in vitro* assays for identifying usable compounds in medicinal research was well known and commonplace. He states that "[u]sing the disclosed *in vitro* assays [taught in the '780 application] would have permitted rapid and routine assessment of test compounds as potential selective Cox-2 inhibitors." Suto Decl. ¶ 24.

According to Dr. Suto, "the ordinary skilled person in September 1992 would have understood the ['780] application to teach that screening for selective inhibitors using the disclosed *in vitro* assays should commence with existing NSAIDs as a starting point." Suto Decl. ¶ 25.[11] He states that a medicinal chemist would have understood, from the '780 application and his knowledge of the relevant art, that one should prepare new compounds based on an initial, NSAID "lead compound." Suto Decl. ¶ 27. The Cox-2 selectivity of the new compounds, which would essentially be variants of the lead compound, would then be compared to that of the lead compound. A researcher would then determine which structural changes to the lead compound increased Cox-2 selectivity, using "routine" methods. Suto Decl. ¶ 28. The most promising compounds would then have been "assessed in several of the many *in vivo* animal models then in use for screening NSAIDs." Suto Dec. ¶ 38.

Although Dr. Suto states that a person of ordinary skill in the art would have understood much of this from reading the '780 application, nowhere does he point to any particular language in the application setting forth how to select compounds that would be likely to be of use in practicing the invention. Instead, he relies – as does plaintiff – on this hypothetical person's knowledge of the art to supply this missing information.

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[11] Dr. Suto states that as an alternative, an ordinary skilled scientist employed by a pharmaceutical corporation would have screened all compounds maintained in the corporate compound "library." Dr. Suto maintains that "[t]his approach ha[s] the potential quickly to identify novel compounds inhibiting the target of interest." Suto Decl.¶ 30.

While it is true that a patent need not disclose that which is already well known in the art in order to be enabling, *see, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947, 107 S.Ct. 1606, 94 L.Ed.2d 792 (1987), the Federal Circuit has cautioned:

> that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.

Genentech, 108 F.3d at 1366.

Here, far more than "minor details" are missing. Neither the patent nor the September 1992 application identify any suitable compound, nor do they explain how one can discover such a compound, except by testing compounds that "include but are not limited to nucleic acid encoding PGHS-2 and homologues, analogues, and deletions thereof, as well as antisense, ribozyme, triple helix, antibody, and polypeptide molecules and small inorganic molecules." '850 Patent, col. 27, lines 29-35. As the Federal Circuit stated in *Genentech*, plaintiff cannot rectify this glaring omission simply by asserting that the necessary information would have been known to one of skill in the

art.[12] 108 F.3d at 1366; *see also Perreira v. Secretary of Dep't of H.H.S.*, 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994)

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[12] I have also considered the declarations of plaintiff's other experts: Edward A. Dennis, who holds a Ph.D. in Chemistry; Christopher J. Schofield, Ph.D., who is a lecturer in Organic Chemistry; Heather M. Wallace, who holds a Ph.D. in Biochemistry; and Eugene Segre, M.D., who has experience in clinical pharmacology and drug development.

Neither Dr. Segre's declaration (Docket # 325) nor Dr. Wallace's declaration (Docket # 327) addresses the issue of enablement with respect to the identification of a suitable compound. Dr. Segre's declaration is primarily concerned with whether "pharmacologists and clinicians, when *provided* by medicinal chemists with a COX-2 selective non-steroidal anti-inflammatory agent," would have been able to determine an appropriate dosage and to actually use it and evaluate its efficacy with human patients. Segre Decl. ¶ 7 (emphasis added). Dr. Wallace's declaration mostly provides background information relating to NSAIDs in general.

Drs. Dennis and Schofield both opine that the '780 application would have enabled one of ordinary skill in the art to practice the inventions claimed in the '850 patent without undue experimentation as of September 1992. Dennis Decl. (Docket # 326) ¶ 34; Schofield Decl. (Docket # 334) ¶¶ 10, 29. The rest of their declarations, however, fail to support that conclusion. Dr. Dennis's declaration, for example, focuses largely on how a person of ordinary skill in the art would understand the use and function of the screening assay, rather than on actually discovering a suitable compound. Likewise, Dr. Schofield offers virtually no explanation of why he believes that the '780 application would have enabled a skilled team of scientists in September 1992 to practice the claimed invention without undue experimentation; his assertion to that effect is wholly conclusory.

I therefore find that these declarations fail to support plaintiff's assertion that the '850 patent meets the enablement requirement. *See Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 876 (Fed. Cir. 1998) (patentee failed, through the statements of its experts, to raise a genuine issue of material fact precluding summary judgment, since "the expert declarations [we]re wholly conclusory, devoid of facts upon which the affiant[s'] conclusions, as experts, were reached"); *Gleason Works v. Oerlikon Geartec, AG*, 141 F.Supp.2d 334, 341 (W.D.N.Y.2001) ("a party cannot defeat a well-founded motion for

(Continued on following page)

("An expert opinion is no better than the soundness of the reasons supporting it").

I also note that several of plaintiff's experts state that, based on their review of certain confidential documents obtained in discovery, as well as a statement of Peter Isakson, an employee of Searle, which was submitted in connection with an unrelated action in Great Britain (Docket # 333, Ex. 12), they believe that Searle used *in vitro* assays that led to the discovery of selective PGHS-2 inhibitors. According to Dr. Suto, Searle's effort to identify such compounds began in August 1992. By May 1993, Searle had screened more than 600 compounds in *in vitro* assays, and had identified a number of selective PGHS-2 inhibitors.

The point, apparently, is to show that researchers at Searle, using the methods taught, and information contained, in the '780 application, were able to identify selective PGHS-2 inhibitors.[13] The fact that it took Searle about eight months to identify some PGHS-2 selective inhibitors, after screening over 600 compounds, however, does not show that the '780 application was enabling in the absence of undue experimentation. While I recognize that the test for undue experimentation is not "merely quantitative," *PPG Indus.*, 75 F.3d at 1564, this nevertheless demonstrates that considerable work and research was needed in order to turn the invention claimed by the '850 patent into reality, and the patent supplies very little

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summary judgment simply by submitting an expert's 'naked opinions' ") (quoting *Weigel v. Target Stores*, 122 F.3d 461, 469 (7th Cir.1997)).

[13] Plaintiff does not explain why, if Searle relied on information set forth in the '780 application, Searle began looking for a PGHS-2 inhibitor in August 1992, a month before the '780 application was filed.

guidance with respect to the direction in which the experimentation should proceed. *See National Recovery Technologies,* 166 F.3d at 1198 ("The most that [the patentee] can be credited with is promising the ideal result in [the patent claims], even though the specification does not completely deliver on this promise").

In short, although the '850 patent describes an assay for determining whether a given compound possesses certain desired characteristics, and identifies some broad categories of compounds that *might* work, these descriptions, without more precise guidelines, amount to little more than "a starting point, a direction for further research." *Genentech,* 108 F.3d at 1366. *See also Calgene,* 188 F.3d at 1374 ("the teachings set forth in the specifications provide no more than a 'plan' or 'invitation' for those of skill in the art to experiment practicing [the claimed invention]; they do not provide sufficient guidance or specificity as to how to execute that plan"); *National Recovery Technologies,* 166 F.3d at 1198 (stating that patent-in-suit "recognizes a specific need . . . and suggests a theoretical answer to that need. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement"). The '850 patent does not describe the claimed invention in terms that will "enable any person skilled in the art . . . to make and use" the invention. At most, its description will enable a person of ordinary skill in the art to *attempt to discover* how to practice the claimed invention. That is not enough.

CONCLUSION

Defendants' motion for summary judgment of patent invalidity for failure to meet the written-description requirement of 35 U.S.C. § 112, ¶ 1 (Docket #170), and defendants' motion for summary judgment of patent invalidity for non-enablement ((Docket # 255) are granted, and the complaint is dismissed.

Plaintiff's cross-motion for summary judgment that the '850 patent is not invalid for failure to meet the written-description requirement (Docket # 207) is denied.

IT IS SO ORDERED.

APPENDIX C

United States Court of Appeals for the Federal Circuit

03-1304

UNIVERSITY OF ROCHESTER,

Plaintiff-Appellant,

v.

G.D. SEARLE & CO., INC., MONSANTO COMPANY, PHARMACIA CORPORATION and PFIZER, INC.,

Defendants-Appellees.

375 F.3d 1303

July 2, 2004, Decided

Gerald P. Dodson, Morrison & Foerster, LLP, of Palo Alto, California, filed a petition for rehearing en banc for plaintiff-appellant. With him on the petition were Emily A. Evans, Erica D. Wilson and Erik J. Olson.

Gerald Sobel, Kaye Scholer LLP, of New York, New York, filed an opposition to the petition for defendants-appellees. With him on the opposition were Richard G. Greco, Sylvia M. Becker and Daniel L. Reisner. Of counsel on the opposition was Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York.

Daniel J. Furniss, Townsend and Townsend and Crew LLP, of Palo Alto, California, filed an amici curiae brief for The Regents of the University of California, et al. With him on the brief were Susan M. Spaeth and Madison C. Jellins.

Appealed from: United States District Court for the Western District of New York

Judge David G. Larimer

ON PETITION FOR REHEARING EN BANC

ORDER

A petition for rehearing en banc was filed by the Appellant, and a response thereto was invited by the court and filed by the Appellees.[1]

This matter was referred first as a petition for rehearing to the merits panel that heard this appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae brief were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for rehearing is denied.

(2) The petition for rehearing en banc is denied.

NEWMAN, *Circuit Judge*, dissents in a separate opinion.

LOURIE, *Circuit Judge*, concurs in a separate opinion.

RADER, *Circuit Judge*, with whom GAJARSA and LINN, *Circuit Judges*, join, dissents in a separate opinion.

LINN, *Circuit Judge*, with whom RADER and GAJARSA, *Circuit Judges*, join, dissents in a separate opinion.

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[1] The Regents of the University of California, et al. filed an amici curiae brief.

DYK, *Circuit Judge*, concurs in a separate opinion.

The mandate of the court will issue on July 9, 2004.

FOR THE COURT

July 2, 2004
Date

Jan Horbaly
Jan Horbaly
Clerk

cc: Gerald P. Dodson, Esq.
Robert L. Baechtold, Esq.
Gerald Sobel, Esq.
Daniel J. Furniss, Esq.
James J. Kelley, Esq.

NEWMAN, *Circuit Judge*, dissenting from the denial of rehearing en banc.

I respectfully dissent from the court's decision not to resolve en banc the burgeoning conflict in pronouncements of this court concerning the written description and enablement requirements of the Patent Act. This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products. The appropriate forum is now the en banc tribunal, not continuing debate in panel opinions applying divergent law.

I fully share Judge Lourie's understanding of the law. The continuing attack on well-established and heretofore unchallenged decisions such as *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("we hereby reaffirm, that 35 U.S.C. § 112, first paragraph, requires a 'written description of the invention' which is separate and distinct from the enablement requirement") and earlier cases such as *In re Ruschig,* 379 F.2d 990 (CCPA 1967) (written

description is one of three distinct requirements under 35 U.S.C. § 112) is not only unwarranted, but is disruptive of the stability with which this court is charged. If precedent has become obsolete or inapplicable, we should resolve the matter as a court and again speak with one voice.

The new biology has indeed raised new and important questions, with implications for policy as well as law. However, the answer is not the simplistic one espoused by some commentators; it is simply incorrect to say that there is not now and never has been a "written description" requirement in the patent law. It has always been necessary to disclose and describe what is patented. It has never been the law that one can claim what is not made known and set forth in the patent.

Various past decisions have been offered to support the exotic proposition that it is not necessary for the inventor to describe the patented invention, but that enablement alone suffices under the statute. These cases concern traditional issues of generic disclosures and specific examples, and questions of support and predictability for scientific concepts and their embodiments. Such traditional law was applied in *Regents of the University of California v. Eli Lilly & Co.* 119 F.3d 1559 (Fed. Cir. 1997), a case that is misdescribed in this debate, for *Lilly* does not depart from precedent in its holding that the written description requirement can be fulfilled by "a precise definition, such as by structure, formula, chemical name, or physical properties." *Id.* at 1565, quoting *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir. 1993).

If the nature of the subject matter is not amenable to precise description, some alternative mode of disclosure is required, such as deposit in a public depository. *Enzo*

Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002). However, the public purpose of patents is seriously disserved by eliminating the description requirement entirely. Federal Circuit law of written description has become encumbered with inconsistent pronouncements, leading me to remark that "[c]laims to an invention that is not described in the specification are an anachronism." *Housey Pharms., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1357 (Fed. Cir. 2004) (Newman, J., dissenting). If the majority of this court is nonetheless sympathetic to that position, there should be careful consideration of the implications of precedent, for the law is that "Section 112 requires that the application describe, enable, and set forth the best mode of carrying out the invention." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 724 (2002).

The issue of whether patent law contains a separate written description requirement has percolated through various panels of this court, on a variety of facts. The differences of opinion among the judges of the Federal Circuit, are, in microcosm, the "percolation" that scholars feared would be lost by a national court at the circuit level. Percolation is the great justifier of conflict among the regional circuits. In the words of the Supreme Court:

> We have in many instances recognized that when frontier legal problems are presented, periods of "percolation" in, and diverse opinions from, state and federal appellate courts may yield a better informed and more enduring final pronouncement by this Court.

Arizona v. Evans, 514 U.S. 1, 24 n.1 (1995). This question has percolated enough; it is ripe for en banc resolution.

LOURIE, *Circuit Judge*, concurring.

I concur in the decision of the court not to rehear this case *en banc*, just as previously the court also declined to hear a written description case *en banc*. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 970-75 (Fed. Cir. 2002). That is because this case was properly decided based on one of the grounds relied on by the district court in invalidating the Rochester patent, *see Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), the analysis of which will not be repeated here.

Contrary to the assertions of the appellant, certain amici, and some of the dissenters, there is and always has been a separate written description requirement in the patent law. The requirement to describe one's invention is basic to the patent law, and every patent draftsman knows that he or she must describe a client's invention independently of the need to enable one skilled in the relevant art to make and use the invention. The specification then must also describe how to make and use the invention (*i.e.*, enable it), but that is a different task.

The requirements of the statute cannot be swept away by claiming that it relates only to priority issues or that the prohibition on introduction of new matter takes care of the need for a written description. The statute does not contain a limitation that it pertains only to priority issues. Moreover, the prohibition on introduction of new matter (35 U.S.C. § 132) is not a substitute for the written description requirement. Section 282 of the Patent Act lists as a defense to an infringement action invalidity arising from a failure to comply with a requirement of section 112 of the Act, which includes written description. In contrast, the new matter provision, section 132, appears in a provision

entitled "Notice of rejection; reexamination." Failure to comply with that section is not expressly listed in the statute as an invalidity defense to infringement, although we have held that the unsupported claims are invalid. *See, e.g., Quantum Corp. v. Rodime, PLC,* 65 F.3d 1577 (Fed. Cir. 1995) (invalidating claims that were broadened in scope during reexamination in violation of 35 U.S.C. § 305, which is analogous to section 132).

The separate written description requirement poses no conflict with the role of the claims. It is well established that the specification teaches an invention, whereas the claims define the right to exclude. *SRI Int'l v. Matsushita Elec. Corp. of Am.,* 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985). While claims must be supported by the written description, the latter contains much material that is not in the claims. The written description contains an elucidation of various aspects of an invention as well as material that is necessary for enablement. Moreover, the written description often contains material that an applicant intended to claim that has been rejected in examination. Thus, the written description and the claims do not duplicate each other.

The fact, if it is a fact, that written description has only been relied upon in recent years as a ground of invalidity does not remove that requirement from the statute. Legal holdings arise when they do because litigants raise them and courts have to decide them. Contrary to what has been asserted, the interpretation of the statute as containing a separate written description requirement did not originate with *Lilly. See Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555 (Fed. Cir. 1991); *In re Ruschig,* 379 F.2d 990 (CCPA 1967). It has always been there. And if a particular scope of claim has not been sustained by the

courts for failure to comply with the written description requirement, it is because the applicant did not describe, and presumably did not invent, the subject matter of the scope sought.

Moreover, it is not correct, as has been asserted, that our decisions, particularly *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), have created a "heightened" written description requirement for biotechnology inventions. We have applied the written description requirement to cases that are not in the fields of chemistry or biotechnology. *See, e.g., In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004) (dental floss); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) (artificial hip sockets); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998) (sectional sofas); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997) (automated sales terminals); *Vas-Cath* (double lumen catheters). The statute is the same for all types of inventions, although it may be applied differently, based on the technology and what is known by one of ordinary skill in the art at the time an invention was made. Indeed, Rochester's claimed invention at issue in the present case is not biotechnological. Although the inventors apparently contemplated that the tools of biotechnology would be used to determine whether a given drug is a COX-2 inhibitor insofar as the specification of the '850 patent describes how to make cell lines that express one or the other of COX-1 and COX-2, that method is claimed in another patent. The claims of this patent are all directed to pharmaceutical methods for selectively inhibiting a natural process in the human body. That is not what one commonly refers to as biotechnology.

It has been noted that genes can be described by their informational function, not just by structure or physical or

chemical properties, and that a lesser written description may be adequate than is required for other types of inventions. Maybe so. Technology progresses, and what one skilled in the art would read from a particular disclosure may change. The PTO has now provided guidelines that help to guide applicants in preparing their patent applications.

It is obviously correct that genes convey information (*e.g.,* to make other nucleic acids or to encode particular proteins). That fact does not serve to deny the existence of a written description requirement in the law. It only goes to whether, under the facts of a particular case, the written description requirement has been met. A fact-finder may have to decide whether claiming a material solely by its information-conveying character results in a "single means claim" purporting to claim everything that works, a dubious fulfillment of the requirement to "distinctly claim the subject matter" of the invention. 35 U.S.C. § 112. In any event, it is fact-intensive. But, once again, these matters go to whether the written description requirement has been met, not whether it exists.

As for the proposition that an original claim is part of the written description, that is clear. *See In re Gardner,* 475 F.2d 1389, 1391 (CCPA 1973). However, the issue may still remain in a given case, especially with regard to generic claims, whether an original claim conveys that one has possession of and thus has invented species sufficient to constitute the genus. Thus, the fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement. *See Enzo,* 323 F.3d at 968-69 ("[R]egardless whether the claim appears in the original specification and is thus supported by the specification as of the filing date,

§ 112, ¶ 1 is not necessarily met. . . . If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification does not save it. A claim does not become more descriptive by its repetition, or its longevity.").

In sum, I concur in the decision of the court not to rehear this case *en banc*. Our precedent is clear and consistent and necessitates no revision of written description law.

RADER, *Circuit Judge*, dissenting from the court's decision not to hear the case en banc, with whom Circuit Judges GAJARSA and LINN, join.

By a narrow margin,[1] this court has declined to take this case *en banc*. Thus, this court avoids the opportunity to clarify and correct its confusing jurisprudence on the new written description invalidity doctrine.

In 1997, this court for the first time applied the written description language of 35 U.S.C. § 112, ¶ 1 as a general disclosure requirement in place of enablement, rather than in its traditional role as a doctrine to prevent applicants from adding new inventions to an older disclosure. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In simple terms, contrary to logic and the statute itself, *Eli Lilly* requires one part of

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[1] Circuit Judges Newman, Rader, Bryson, Gajarsa, and Linn voted in favor of *en banc* reconsideration. Chief Judge Mayer and Circuit Judges Michel, Lourie, Clevenger, Schall, Dyk, and Prost voted against *en banc* reconsideration.

the specification (the written description) to provide "adequate support" for another part of the specification (the claims).[2] Neither *Eli Lilly* nor this case has explained either the legal basis for this new validity requirement or the standard for "adequate support." Because this new judge-made doctrine has created enormous confusion which this court declines to resolve, I respectfully dissent.

Confusion in This New Validity Doctrine

A recent case illustrates well the confusion engendered by this new doctrine. In *Enzo Biochem, Inc. v. Gen Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), this court struggled over the scope of the written description invalidity doctrine first created in 1997. *Eli Lilly,* 119 F.3d at 1559. In its original *Enzo* opinion, 285 F.3d 1013 (Fed. Cir. 2002), this court invalidated claims to polypeptides that detect the gonorrhea bacteria. The inventor of these DNA probes specifically disclosed them and deposited three polypeptides at the American Type Culture Collection. Even for claims limited in scope to the deposited material, this court invalidated the patent for insufficient disclosure of the invention. *Id.* at 1022 (concluding that "a deposit is

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[2] This new validity requirement conflicts with binding precedent because the CCPA made clear that original claims are part of the original disclosure of an invention and thus have no "description" problems. *In re Koller,* 613 F.2d 819, 823 (CCPA 1980) ("[O]riginal claims constitute their own description."); *In re Smith,* 481 F.2d 910, 914 (CCPA 1973) ("Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."); *In re Gardner,* 475 F.2d 1389, 1391 (CCPA 1973) ("Claim 2, which apparently was an original claim, in itself constituted a description in the original disclosure .... Nothing more is necessary for compliance with the description requirement.")

not a substitute for a written description of the claimed invention" (quotation omitted)). This decision correctly applied the 1997 *Eli Lilly* doctrine which requires a nucleotide-by-nucleotide recitation of the structure of a biotechnological invention. *Eli Lilly,* 119 F.3d at 1567. Accordingly, the mere deposit of material did not satisfy that reading of 35 U.S.C. § 112, ¶ 1. *Enzo,* 285 F.3d at 1022.

That *Enzo* opinion caused an immediate firestorm. *See, e.g.,* Brief of Amicus Curiae United States at 1, *Enzo Biochem, Inc. v. Gen Probe, Inc.,* 323 F.3d 956 (Fed. Cir. 2002). Within a few months, this court vacated its original opinion and reversed the result. *See Enzo Biochem, Inc. v. Gen Probe, Inc.,* 323 F.3d 956 (Fed. Cir. 2002). This flip-flop shows the problem. The Director of the Intellectual Property program at the George Washington University Law School stated it concisely: "[S]ince the first panel opinion faithfully followed *Eli Lilly,* and the result is obviously wrong, the *Eli Lilly* description doctrine is itself misguided." Martin J. Adelman, *If Eli Lilly Is Good Law, Didn't the Withdrawn Panel Opinion in Enzo Biochem Have It Right?,* at 2 (2003) (unpublished paper prepared for the 11th Annual Conference on International Intellectual Property Law and Policy at Fordham University, April 24-25, 2003).

Following issuance, withdrawal, and reissuance of *Enzo,* this court engaged in lengthy debate over the new disclosure validity doctrine. *Enzo Biochem,* 323 F.3d at 971-75 (Lourie, J., concurring in decision to not hear the case *en banc*); *id.* at 975 (Newman, J., concurring); *id.* at 975-76 (Dyk, J., concurring); *id.* at 976-87 (Rader, J.,

dissenting)[3]; *id.* at 987-89 (Linn, J., dissenting). That debate continued in this court's subsequent cases. *See, e.g., Moba B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1323 (Fed. Cir. 2003) (Rader, J., concurring) (explaining that juries face the "cumbersome task" of deciding that "the patent's disclosure can enable a skilled artisan to make and practice the entire invention, but still not inform that same artisan that the inventor was in possession of the invention").

Indeed a brief survey of the literature on this topic, an astounding amount in a few short years, shows 31 articles criticizing the *Eli Lilly* doctrine, 7 articles defending the doctrine, and 16 neutrally commenting on the state of this evolving case law.[4] In its brief requesting *en banc* reconsideration in *Enzo Biochem,* the United States issued a call for clarity, which this court has yet to address:

> Although this Court has addressed the "written description" requirement of section 112 on a number of occasions, its decisions have not taken

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[3] This opinion will not repeat the points made earlier about the legal sufficiency of the *Eli Lilly* doctrine. Some of those points include: First, the statutory language and legal precedents make enablement the only substantive test (other than best mode) in the first paragraph of § 112. *Enzo Biochem,* 323 F.3d at 977. Second, this court's predecessor first separated written description from enablement in 1967, but only to police priority. *Id.* Third, this court and its predecessor consistently limited the written description requirement to priority cases, expressly equating the proscription on new matter with written description. *Id.* at 977-79. Lastly, the vague and ill-defined written description requirement threatens to supplant the well-established enablement requirement, which disproportionately affects biotech inventions. *Id.* at 981-83.

[4] An appendix to this opinion summarizes this academic commentary.

> a clear and uniform position regarding the purpose and meaning of the requirement. . . . A review of the plain text of section 112, and the case law of this Court, reveals at least three different possible tests for an adequate "written description." . . . *En banc* consideration of the written description provision is appropriate so that the court can provide inventors, the public, and the USPTO with an authoritative interpretation of the provision.

Brief of Amicus Curiae United States at 4-5, 9.

In sum, by any measure, the *Eli Lilly* doctrine has engendered confusion. After all, *Eli Lilly* created a new validity doctrine under 35 U.S.C. § 112, ¶ 1 separate from enablement and yet described it as "analogous to enablement." 119 F.3d at 1569. Unfortunately, this court has passed up another opportunity to resolve the confusion.

Supreme Court's Role in the *Eli Lilly* Doctrine

In an effort to supply some coherent basis for its new validity doctrine, this court in *Rochester* refers to an 1822 Supreme Court case that discusses the written description language of the Patent Act. *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 924 (Fed. Cir. 2004). An examination of *Rochester*'s references to the Supreme Court in their proper historical context impeaches, rather than supports, the modern written description validity doctrine.

In 1793, the Patent Act, 1 Stat. 318, required an inventor to describe the scope of the invention in the body of the specification; the Act did not require any claims. Instead the Act required the inventor to provide "a written

description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science . . . to make, compound, and use the same. . . ." *In re Barker,* 559 F.2d 588, 592 (CCPA 1977) (ellipses in original). Without citing this statutory language, *Rochester* recounts the Supreme Court's explanation that this provision contained two requirements:

> The specification, then, has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.

Evans v. Eaton, 20 U.S. 356, 433-34 (1822). For obvious reasons, *Rochester* undertakes no further explanation of the Supreme Court's language. In simple terms, the Supreme Court could not have meant that the written description portion of the specification must provide adequate support for the claims as this court's law presently requires. Patents did not even contain claims in 1822.

In fact, even the Supreme Court's allusion to "two objects," the reason for the *Rochester* cite, takes on a different meaning under careful legal analysis. The Supreme Court clearly linked its "other object" of the specification

disclosure to the portion of the statute requiring the inventor "to distinguish the same from all things before known." *Evans,* 20 U.S. at 430. Significantly, that language no longer appears in 35 U.S.C. § 112. Later in 1870, the Patent Act first articulated the requirement that applicants define their exclusive right in a distinctly drafted claim. Act of July 8, 1870, Ch. 230, 16 Stat. 198. Only one logical conclusion flows from this history. When the Patent Act assigned the notice function to claims rather than the written description, enablement became the sole 35 U.S.C. § 112, ¶ 1 standard for adequate disclosure of an invention.[5] *See Enzo Biochem*, 323 F.3d at 977. This observation about the meaning of 35 U.S.C. § 112, ¶ 1 has been axiomatic patent law for decades. In a decision of the Court of Customs and Patent Appeals that is binding on this court, Judge Rich interpreted 35 U.S.C. § 112, ¶ 1 to have only two requirements – not enablement and the *Eli Lilly* written description doctrine, but enablement and best mode! *In re Gay,* 309 F.2d 769, 772 (CCPA 1962). In sum, the *Eli Lilly* written description doctrine has no basis in this court's legal precedent. Thus, *Rochester* cannot explain the missing 1793 statutory language, the advent of the claim requirement that replaced the 1822 description doctrine, the inapplicability of the *Evans* quote to a new

[5] Indeed the United States notes that the current statute requires "a written description of the invention, and *of the manner and process of making and using it,* in such full clear, concise, and exact terms *as to* enable [the invention]." 35 U.S.C. § 112, ¶ 1 (emphasis added). As the United States noted, "A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention." Brief of Amicus Curiae United States at 5, *Enzo Biochem, Inc. v. Gen Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002).

1997 invalidity doctrine, or the apparent conflict with binding CCPA interpretations of 35 U.S.C. § 112, ¶ 1.

The *Rochester* reference to the 1822 Supreme Court language does, however, reveal some insights into the reasons that the *Eli Lilly* doctrine engenders confusion. As the 1822 Supreme Court reference explains, the original statute required a written description to warn "an innocent purchaser or other person using a machine, of his infringement." *Evans,* 20 U.S. at 434. In other words, the statute incorporated a written description requirement to define the scope of the invention for infringement and for distinguishing the invention from prior art. *Eli Lilly* and its progeny convert that original infringement doctrine into a new challenge to validity. Suddenly, all the difficulty and imprecision of defining an invention in legal language, *see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 731 (2002), becomes a validity doctrine.

In sum, a careful legal analysis of the language and history of 35 U.S.C. § 112, ¶ 1 shows that the *Eli Lilly* doctrine has no basis in the written description language of the original Patent Act. Moreover, as this court's binding CCPA precedent shows, the statutory language of 35 U.S.C. § 112, ¶ 1 has not changed in any way that justifies "discovery" of a vast new validity doctrine over two hundred years after the 1793 Act. To the contrary, the changes in the statutory language of § 112, ¶ 1 since 1793 impeach the reasoning of *Rochester* and *Eli Lilly.*

Rochester also refers to the Supreme Court's listing of patent requirements in *Festo. Rochester,* 358 F.3d at 921 (quoting *Festo,* 535 U.S. at 736). In the first place, the *Festo* listing is just that, a passing reference to some of the requirements of the Patent Act. The passing reference, for

instance, does not even mention some binding requirements, e.g., subject matter eligibility and claim definiteness. In fact, in another post-*Eli Lilly* listing of Patent Act requirements, the Supreme Court acknowledged only enablement as the disclosure *quid pro quo* of the statute: "In addition [to novelty, utility, and nonobviousness], to obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001). A careful analysis of the Supreme Court's passing recitations of patent requirements does not support the *Eli Lilly* doctrine.

Rochester's invocation of the *Festo* listing of a "disclosure" requirement, however, betrays a telling incompleteness in its reasoning. The Supreme Court is entirely correct to acknowledge the requirement of full "disclosure" *at the time of invention* that prevents updating the patent document with later inventions. Beginning in 1967, this court and its predecessor applied the written description language to achieve this vital purpose of the Patent Act – tying disclosure to the time of invention. *In re Ruschig,* 379 F.2d 990 (CCPA 1967); *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555 (Fed. Cir. 1991). In the words of Judge Rich, the first judge to use the description requirement to police priority, "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter *later* claimed by him." *In re Wertheim,* 541 F.2d 257, 262 (CCPA 1976) (emphasis added). In fact, every application of the written description doctrine before *Eli Lilly* in 1997 applied the written description doctrine for this important purpose and only for this important purpose.

Enzo, 323 F.3d at 984-87 (listing every written description case in the CCPA and Federal Circuit). Thus, the *Festo* listing does not endorse the *Eli Lilly* innovation, but properly invokes the necessity of tying disclosure to the time of invention. In its attempt to support the 1997 doctrine, however, *Rochester* invokes *Vas-Cath* and other Federal Circuit decisions without noting the proper context of those decisions.

In sum, the Supreme Court offers no comfort to the *Eli Lilly* doctrine. Rather, in proper historical and legal context, the Supreme Court's allusions to the description requirement impeach both *Rochester* and *Eli Lilly*.[6]

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[6] Moreover, the pre-1967 CCPA cases mentioned in *Rochester* also shed little light on the modern written description requirement. For instance, *Jepson* does not evince support for *Eli Lilly*. Rather, *Jepson*, which does not expressly mention written description at all, decided an interference – a priority dispute – between an application with an earlier filing date and an issued patent with a later filing date. The CCPA held that because the earlier application did not support the claims that were copied from the later patent, the patent was entitled to priority. *Jepson v. Coleman*, 314 F.2d 533 (CCPA 1963). Thus, *Jepson*, if at all relevant to written description, was a priority case in the traditional mode of written description jurisprudence. The CCPA decided the *Moore* case on obviousness grounds; the description commentary in that case is dicta. *In re Moore*, 155 F.2d 379, 381 (CCPA 1946) (noting that the claims were "properly rejected on the prior art"). The CCPA decided the *Sus* case under paragraph 2 of § 112, not paragraph 1. *In re Sus*, 306 F.2d 494, 496 (CCPA 1962). The reason *Sus* and *Moore* do not appear on the "written description" landscape is because subsequent case law made it clear that, outside the priority context, the substantive test for compliance with the first paragraph of § 112 is enablement. *In re Borkowski*, 422 F.2d 904, 909 (CCPA 1970). Indeed, *Rochester* seems to do a disservice to the CCPA's own acknowledgement that Judge Rich inaugurated the written description requirement to police priority in 1967. *In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981).

The Hypothetical Policy Analysis

Rochester refers to a situation where a patent can enable an invention that is not described by the specification. In the words of the opinion, "[s]uch can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B *if* B were described." *Rochester,* 358 F.3d at 921 (emphasis original). This hypothetical seems to suggest that the 1997 doctrinal creation closes a major gap in patent law. To the contrary, this court only created the *Eli Lilly* requirement in 1997; the patent system had succeeded quite well for over two hundred years without it. Moreover no other patent system in the world has the *Eli Lilly* requirement to this day. The world's patent systems work quite well without it.

The hypothetical actually facilitates a policy analysis that explains the reasons that the new 1997 requirement is both superfluous and dangerous. In the first place, the hypothetical rarely, if ever, happens. No actual case presents the hypothetical. In both *Eli Lilly* and *Rochester,* for instance, the invention A (rat insulin in *Eli Lilly;* an assay for Cox 1 and 2 in *Rochester*) was enabled and described, but the invention B (human insulin in *Eli Lilly;* a Cox 2 inhibitor in *Rochester*) was not enabled.

In understandable terms, the hypothetical says that an inventor invents the radio, but his invention solves a problem that enables those of ordinary skill in the art to know how to make and use both a radio and a TV. His patent disclosure only describes a radio but he claims broadly an "electrical receiver." Thus, his claims seem to encompass the TV which his specification does not describe but would enable if it were described. In that

context, the reason the hypothetical does not occur becomes obvious. If everyone of *ordinary* skill in the art knows from the disclosure how to make and use the TV, the exceptionally talented inventor will also. To avoid any risk of losing the TV invention, the inventor will fully disclose it and claim it, probably in a separate application. For this very practical reason, no case has ever presented the hypothetical. Inventors know when they have made an invention and realize that they must properly disclose it or risk losing it entirely.

Carrying the genuinely "hypothetical" hypothetical forward, however, what happens if the radio inventor for some unfathomable reason does not grasp that he has enabled a TV and later asserts the radio patent against a TV maker? In simple terms, a court would properly interpret the claim as limited to the radio. The TV maker would not infringe a claim that covers only the radio. On the other hand, the *Eli Lilly* doctrine would instead invalidate the radio patent. Is that the best result? After all, the inventor did invent the radio. Should he lose everything because he did not disclose the TV?

The facts of *Eli Lilly* itself illustrate the real problems in this area of patent interpretation and enforcement. In simple terms, the inventor in that case invented and disclosed rat insulin but not human insulin. In fact, at the dawn of the biotechnological age in 1977, the inventor could not make human insulin. Biotechnology was in its infancy; it would have taken months, if not years, of experimentation to make human insulin. Nonetheless the inventor claimed the rat insulin invention broadly and later asserted it against human insulin. In this setting, U.S. patent law (and world patent law in general) has two complementary ways to prevent any injustice – enablement

and traditional (not *Eli Lilly*) written description (enforcing the actual time of invention). If the inventor has not enabled human insulin in the specification, the inventor has not enabled the full scope of the claim. By the way, as noted earlier, if the rat insulin inventor had invented human insulin as well, he surely would have disclosed it. In other words, a lack of disclosure is a dead give-away for enablement problems. Alternatively, or likely in conjunction, the traditional written description requirement as applied by this court and its predecessor beginning in 1967 will prohibit any addition of new matter to the patent document to "update" the claims to cover human insulin. *See, e.g., Chiron Corp. v. Genentech, Inc.,* 363 F.3d 1247 (Fed. Cir. 2004).

In sum, our patent law (and the world's patent law) has worked well for 200 years because the law already possesses ample remedies for the *Rochester* hypothetical, which, as a practical matter, never occurs. Neither *Eli Lilly* nor *Rochester* explains the legal policy that supports the new doctrine.

The Practical Problems

By its terms, the *Eli Lilly* doctrine stated: "An adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties.'" 119 F.3d at 1566 (quoting *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed. Cir. 1993)). In sum, *Eli Lilly* asserts a new free-standing validity requirement. Based on the absence of a nucleotide-by-nucleotide recitation in the specification of the human insulin cDNA, the court determined that the applicant had not adequately described the invention. Thus, the failure to actually

sequence the nucleotides prevents an applicant from claiming a new and useful polypeptide.

This new 1997 rule changes the established rules of claiming and disclosing inventions. Many biotechnological inventions predate *Eli Lilly*. Before the 1997 change, no inventor could have foreseen that the Federal Circuit would make a new disclosure rule. Without any way to redraft issued patents to accommodate the new rule, many patents in the field of biotechnology face serious and unavoidable validity challenges simply because the patent drafter may not have included the lengthy nucleotide sequences. After all, the sequences are often routinely available (albeit at some cost) to those of ordinary skill in this art.

The *Eli Lilly* doctrine also seems to impose some illogical requirements on patent drafters today. Must a software patent disclose every potential coding variation that performs a claimed function? Must a biotechnological invention list every amino acid variation for a particular protein or protein function – a task conceivably as impractical as the software disclosure requirement? Must a university or small biotech company expend scarce resources to produce every potential nucleotide sequence that exhibits their inventive functions? Perhaps more important for overall patent policy, must inventors spend their valuable time and resources fleshing out all the obvious variants of their last invention instead of pursuing their next significant advance in the useful arts? Again *Eli Lilly* and *Rochester* appear to have given little thought to these unintended consequences.

This court, however, is not even the only judicial institution that must deal with the unintended consequences of

the 1997 doctrine. Under this new disclosure test, every case where the written description does not specifically disclose some feature of the claimed invention will give rise to a validity challenge. Thus, trial courts will have to empanel juries to inquire whether one of skill in the art would have known that the inventor "possessed" the full invention. In a sense, the *Eli Lilly* doctrine converts this court's confusing case law about the role of the specification in defining the invention into a validity question. Thus, trial courts as well must struggle to discern the standard for sufficient disclosure of an invention.

Rochester emphasizes that this new disclosure doctrine is different from enablement. *Rochester,* 358 F.3d at 921. Thus, a trial court, as in this case, must first ask its jury whether the specification provides sufficient information to enable one of ordinary skill in the art to make and use the invention. Then the trial court must ask the jury again to look at the same specification for information that an inventor of extraordinary skill "possessed" the invention. Under this court's law, a patent disclosure could apparently enable one of ordinary skill to make and practice the entire invention, but still not inform that same artisan that the inventor was in possession of the invention. Moreover, the trial court must give separate instructions and entertain separate witnesses on these inseparable patent rules to ensure adequate disclosure. Viewed in the practical terms of trial procedure and jury understanding, this 1997 doctrine unnecessarily complicates and prolongs patent enforcement. In sum, *Rochester* does not resolve any of the confusion or provide a sound legal basis for the *Eli Lilly* doctrine. For these reasons, this court should have reviewed this case *en banc.*

Appendix

Defending *Eli Lilly* Written Description

Citation	Quotation
Paula K. Davis, *Questioning the Requirement for Written Description: Enzo Biochem v. Gen-Probe and Overly Broad Patent Cases*, 37 Ind. L. Rev. 467, 500 (2004)	By strictly requiring written description of the invention, the public is guaranteed that the inventor was in possession of the invention when the patent application was filed. In effect, the written description defines the scope of the invention – the metes and bounds that will be given exclusivity.
F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. Rev. 55, 99 (2003)	The U.S. Court of Appeals for the Federal Circuit's strong reading of the written description requirement to put the public on clear notice of what will infringe and what will not makes sense because the patentee, as the drafter, is the least-cost avoider of such ambiguities. This legal development was controversial to be sure; yet it marks an important weapon in the system's arsenal for fighting social cost.

Cynthia M. Lambert, Note: *Gentry Gallery and the Written Description Requirement*, 7 B.U. J. Sci. & Tech. L. 109, 139 (2001)	Although there may be negative effects resulting from a stricter written description standard, including narrowed patent scope and a potential tragedy of the anticommons, the stricter standard is the better choice in terms of fairness to the public because it prevents inventors from overreaching.
Daniel P. Chisholm, Note: *The Effect of the USPTO's Written Description Guidelines on Gene Patent Applications*, 35 Suffolk U. L. Rev. 543, 570 (2001)	Absent this heightened interpretation, broadly construed claims would allow applicants to obtain exclusive rights to products in which they do not actually possess. Granting such broad claims would stifle the very purpose of the United States patent system: preserving incentives for continued innovations.
Margaret Sampson, Comment: *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233, 1273 (2000)	The use of a heightened written description requirement by the Federal Circuit to define and limit the scope of claimed inventions preserves incentives for continued innovation.

Mark J. Stewart, Note: *The Written Description Requirement of 35 U.S.C. 112(1): The Standard After Regents of the University of California v. Eli Lilly & Co.*, 32 Ind. L. Rev. 537, 563 (1999)	Through application of the written description requirement, courts can distinguish between claims to technologies that are too broad or basic to justify patent protection, and those dealing with other types of technologies that are more predictable and may justify broader protection.
Emanuel Vacchiano, Comment: *It's a Wonderful Genome: The Written-Description Requirement Protects the Human Genome from Overly-Broad Patents*, 32 J. Marshall L. Rev. 805, 832 (1999)	Fortunately, the CAFC narrowly construes patent rights based on disclosures of DNA sequences, and as a result, will likely invalidate patent claims based on EST disclosures that contain a broad scope of protection encompassing a gene or even an entire protein-coding segment of a cDNA.

Criticizing *Eli Lilly* Written Description

Citation	Quotation
Stephen J. Burdick, Note: *Moba v. Diamond Automation, Inc.: Questioning the Separate Written Description Requirement*, 19 Berkeley Tech. L.J. 133, 151 (2004)	*Moba* illustrates the problems associated with the separate written description requirement. The judge-made doctrine does not contribute any additional value to the other patentability requirements. Its effects are redundant with the enablement and new matter requirements of patent law. Additionally, the written

	description requirement creates confusion and discourages patenting and innovation. The Federal Circuit should dispose of the separate written description requirement entirely.
Martin J. Adelman, 3-2 Patent Law Perspectives § 2.9 (2004)	[T]he original panel opinion in *Enzo Biochem* is correct if we assume that *Eli Lilly* is sound law, since *Eli Lilly* holds that the failure to actually detail the sequence of nucleotides of a polypeptide prevents an applicant from claiming it. Obviously merely depositing a polypeptide does not disclose its sequence without a sequencing operation. Thus a disclosure that effectively puts the polypeptide in possession of the public by virtue of providing a set of directions for obtaining it should not be treated differently than an inventor who puts the polypeptide in a depository without sequencing it. Since this is a result that is difficult to defend, it proves that the *Eli Lilly* doctrine is itself misguided. It is thus time to formally overrule it along with *In re Deuel* another case that holds that the act of sequencing is the key to patentability.

Harold C. Wegner, *The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years*, 37 Akron L. Rev. 243, 244 (2004)	The first problem here is the judicial activism from several panel opinions that created a "written description" requirement apart from the original "new matter" proscription.
Jennifer L. Davis, Comment: *The Test of Primary Cloning: A New Approach to the Written Description Requirement in Biotechnological Patents*, 20 Santa Clara Computer & High Tech. L.J. 469, 487-88 (2004)	The court has not issued clear and consistent standards. In fact, the court itself appears confused over the proper standards by which to judge the adequacy of a written description as reflected by the recent decision in *Enzo I* followed by a reversal upon rehearing in *Enzo II*. . . .
Martin J. Adelman, *If Eli Lilly Is Good Law, Didn't the Withdrawn Panel Opinion in Enzo Biochem Have It Right?*, at 2 (2003) (unpublished paper prepared for the 11th Annual Conference on International Intellectual Property Law and Policy at Fordham University, April 24-25, 2003).	[S]ince the first panel opinion [in *Enzo*] faithfully followed *Eli Lilly*, and the result reached is obviously wrong, the *Eli Lilly* description doctrine is itself misguided.
Duane M. Linstrom, *Spontaneous Mutation: A Sudden Change in the Evolution of the Written Description Requirement as It Applies to Genetic Patents*, 40 San Diego L. Rev. 947, 970 (2003)	In sum, the latest *Enzo* decision has shifted the direction of the development of the written description requirement for DNA patents, but it has also left us with even more uncertainty in the law than before the ruling.

Jennifer Gordon, Ph.D., *Preparing and Prosecuting a Patent That Holds Up in Litigation*, 766 PLI/Pat 873, 907-08 (2003)	Until the dissenters can persuade the Court to review the *Lilly* written description rule en banc, the Federal Circuit can continue to apply the *Lilly* standard to invalidate any patent, regardless of whether priority is an issue, where the written description does not show possession of the invention at the time of filing.
Rachel Krevans and Cathleen Ellis, *Preparing for Biotech Patent Litigation*, 760 PLI/Pat 529, 555-56 (2003)	The Federal Circuit doctrine that makes enablement a separate requirement from the written description requirement contradicts the plain language of the statute.
John C. Stolpa, Case Comment: *Toward Aligning the Law with Biology? The Federal Circuit's About Face in Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 4 Minn. Intell. Prop. Rev. 339, 366 (2003)	The Federal Circuit should take the next available opportunity to overrule the *Eli Lilly* decision through an *en banc* hearing and return enablement as the sole substantive disclosure requirement of *35 U.S.C. 112*, paragraph 1. The heightened written description standard applied to biotechnology inventions after *Eli Lilly* ignores fundamental biological principles and focuses too much attention on the structure of a DNA or protein. In addition, the standard is inflexible to technological changes and requires constant updating that leads to uncertainty over patent validity.

	Finally, the heightened requirement fails to meet the constitutional purpose behind the patent laws by discouraging full disclosure of biological inventions. Simply returning to the enablement disclosure standard that was in effect prior to *Eli Lilly* would solve the bulk of these problems.
Laurence H. Pretty, Patent Litigation § 1:3.3, Defenses Against Patent Validity, 1-44 (2003)	The term "written description" appears grammatically as the subject for the verb "enable" in the enablement section of 35 U.S.C. § 112. However, the written-description requirement has been judicially construed to have a separate and additional purpose.
Stephen R. Albainy-Jenei and Karlyn A. Schnapp, *Early-Stage Companies Face New Challenges Rochester Case Limited the Patentability Of Reach-Through Claims*, 12/8/03 Nat'l L.J. S3, col. 1, S3, col. 1+ (2003)	While *Rochester* is on appeal to the U.S. Court of Appeals for the Federal Circuit, it is likely that such reach-through claims will remain severely restricted, possibly hurting the value of intellectual property for many early-stage biotechnology companies. * * * In addition, the overall cost in legal fees for drafting and prosecuting more carefully crafted, fully detailed biotechnology applications will only increase for complex inventions. While big pharmaceutical companies will have the money to spend in such

	endeavors, it will be the universities and the small biotech start-ups that will most certainly be affected since these institutions historically do not have the resources, both financial and in personnel, to overcome this new set of obstacles in trying to obtain patent protection for their scientific contributions in an ever-changing landscape.
Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1652-54 (2003)	In biotechnology, however, the doctrine has been applied as a sort of "super-enablement" requirement, forcing biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences. The written description doctrine as currently applied is a macro policy lever. The Federal Circuit has applied the doctrine to biotechnology cases in a way that would be inconceivable in other industries, such as software. The effect is to narrow the scope of biotechnology patents – or at least DNA patents – rather dramatically.
Warren D. Woessner, *"Do-Over!" – The Federal Circuit Takes a Second Look at Enzo v. Gen-Probe*, 85 J. Pat. & Trademark Off. Soc'y 275, 285 (2003)	It is time for the court to deliver *Lilly* and *Enzo (I)* to the doctrinal scrap heap where holdings like *Durden* and *Druey* ended up, and let the evolution of biotechnology patent law continue in a productive direction.

Robert L. Harmon, *Must a Patent Describe an Accused Infringement?*, 85 J. Pat. & Trademark Off. Soc'y 153, 154 (2003)	In the meantime, however, we are confronted with a welter of confused and confusing precedent that not only defies restatement, but renders analysis and synthesis distinctly unmanageable. The only approach the author has found to making some sense of the situation is to ask what the motivation of the Federal Circuit is in its efforts to restrict this once well-recognized tenet of patent law.
Sven J.R. Bostyn, *Written Description After Enzo Biochem: Can the Real Requirement Step Forward Please?*, 85 J. Pat. & Trademark Off. Soc'y 131, 151 (2003)	The third way is to limit the application of the written description requirement to cases where priority issues are involved, and limiting it to these issues, leaving the bulk of the disclosure evaluation to the enablement requirement, the key feature of the quid pro quo of the patent system. In the author's view, that ought to be the optimal solution, leading to a coherent and stable patent system, both for patent applicants and for patent offices and courts. In this light, it would have been a good opportunity to hear the *Enzo* case *en banc*.

David Kelly, Comment: *The Federal Circuit Transforms the Written Description Requirement into a Biotech-Specific Hurdle to Obtaining Patent Protection for Biotechnology Patents*, 13 Alb. L.J. Sci. & Tech. 249, 270 (2002)	The Federal Circuit's decision in *Lilly*, however, has fashioned the description requirement into a barrier to scientific progress in the field of biotechnology. This heightened standard, applied exclusively to biotechnology patents, will likely have an adverse effect on the progress of biotechnological innovations. Rather than awarding patent protection to the discoverers of new and useful genes, *Lilly* rewards those who first sequence the gene accurately. The result will be patent protection to those who can sequence DNA the fastest, not to those who invested their life's work locating the gene.
Eli A. Loots, *The 2001 USPTO Written Guidelines and Gene Claims*, 17 Berkeley Tech. L.J. 117, 134 (2002)	Some conflict between patent prosecution and patent litigation is inevitable. However, the current conflict has been recognized as a widening gulf between the norms of the scientific community and those of the legal system.
Limin Zheng, *Purdue Pharma L.P. v. Faulding Inc.*, 17 Berkeley Tech. L.J. 95, 103 (2002)	The court's continuing use of an inconsistent and often overly-stringent written description requirement leaves inventors, especially those in the pharmaceutical industry, with little incentive to disclose, and is likely to discourage inventors from seeking patent protection.

Jeffie A. Kopczynski, Note: *A New Era for 112? Exploring Recent Developments in the Written Description Requirement as Applied to Biotechnology Inventions*, 16 Harv. J. Law & Tech. 229, 230 (2002)	Recent Federal Circuit patent cases have held biotechnology inventions to a higher written description standard than inventions in other areas, such as the mechanical arts. . . . This perception of unpredictability has caused the Federal Circuit to apply a heightened written description requirement to biotechnology patents. This paper argues that the written description requirement for patents should not be applied differently to inventions in different disciplines.
Shraddha A. Upadhyaya, *The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims*, 4 Minn. Intell. Prop. Rev. 65, 120-21 (2002)	The postmodern trilogy unjustifiably departs from precedent in order to meet the increasing intellectual difficulties of biotechnology patents. The sophisticated obviousness function simply will not bar biotechnology patents, but a simple written description requirement will. This anomaly is troublesome. The written description requirement cannot and should not serve any function other than to guarantee that subsequently filed claims are entitled to the benefit of the original application.

Sheila R. Arriola, *Biotechnology Patents After Festo: Rethinking The Heightened Enablement and Written Description Requirements*, 11 Fed. Circuit B.J. 919, 951 (2002)	The problem created by the Federal Circuit could be remedied by overruling the prior biotechnology enablement and written description case law that heightened these requirements on the basis of the state of technology at the time of those decisions. The USPTO could then relax the enablement and written description requirements with respect to proteins and their analogs. Not only would this shift the determination of patent scope from judges back to the USPTO's biotechnology examiners, but it would force patentees to protect their inventions proactively through continuations and CIPs, rather than reactively through the doctrine of equivalents. On balance, the long-term costs of this proposed approach are far less than those that *Festo* and the heightened enablement and written description requirements will have on patent protection, and ultimately, on the biotechnology industry as we know it.

Robert A. Hodges, Note: *Black Box Biotech Inventions: When a "Mere Wish Or Plan" Should Be Considered an Adequate Description of the Invention*, 17 Ga. St. U. L. Rev. 831, 860 (2001)	The Federal Circuit's imposition of a heightened standard for the written description of DNA inventions in *Eli Lilly* increases the gap between the written description requirement for biotech inventions and the realities of how such inventions are produced.
Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 Harv. J. Law & Tech. 267, 313 (2000)	If courts are strengthening the written description and enablement requirements in order to limit biotechnology patents, this fact raises concerns about creating special standards for particular areas of technology. If it is the courts that impose these standards, pioneering scientists in a new field will be unable to determine, when applying for patents, to what standard their patents will eventually be held when they are litigated.
Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 Wash. U. J.L. & Pol'y 55, 107 (2000)	As a first step, the Federal Circuit might simply admit that the written description requirement is redundant of enablement. This would at least allow for a more forthright exploration of the question whether redundancy in patent disclosure requirement remains tolerable. The Federal Circuit could reach the conclusion,

	perhaps, that the written description requirement simply provides a fail-safe mechanism that judges (or examiners) may use in their discretion in hard cases.
Salima Merani, *Hyatt v. Boone*, 14 Berkeley Tech. L.J. 137, 146 (1999)	Admittedly, the Federal Circuit has used different expressions in describing a sufficient written description. Judge Newman, however, "[did] not view these various expressions as setting divergent standards for compliance with [section] 112." She emphasized that, in all cases, the purpose of the written description requirement was to ensure that the inventor had possession of the claimed invention at the time of the application filing date. Analysis of historical and policy rationale of section 112 supports Judge Newman's view of the written description requirement.
Zhibin Ren, Note: *Confusing Reasoning, Right Result: The Written Description Requirement and Regents of the University Of California v. Eli Lilly & Company*, 1999 Wis. L. Rev. 1297, 1324 (1999)	In *Lilly*, the Federal Circuit deviated from the well-established traditional written description standard and adopted an ad hoc approach to conduct a written description analysis for DNA claims. This approach allows the court to use whatever is handy to justify the result it wants to reach.

Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology, 34 Wake Forest L. Rev. 827, 835 (1999)*	In essence, the *Lilly* court used the written description requirement as a type of elevated enablement requirement. An ordinary enablement challenge to the University of California's claim was not raised (and, if raised, probably would have failed) because it would have been relatively easy for a person of ordinary skill in the art to use the rat insulin cDNA that Lilly had already sequenced to "fish out" the human cDNA from a cDNA library.
Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615, 615-16 (1998)	The *Lilly* decision may profoundly limit the scope of protection available for new gene inventions; . . . *Lilly* aptly illustrates the increased widening of the gulf between the norms of the business and scientific communities and the U.S. patent system, as users of the latter come to understand that the patent system no longer reflects the realities of scientific contribution.
Michael Delmas Plimier, *Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co.*, 13 Berkeley Tech. L.J. 149, 161 (1998)	The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless.

Harris A. Pitlick, *The Mutation on the Description Requirement Gene, 80 J. Pat. & Trademark Off. Soc'y 209, 209-10 (1998)*	The recent decision in *Regents of the University of California v. Eli Lilly and Co.*, on top of *Fiers v. Revel*, decided only a few years before, are such extreme departures from conventional description requirement jurisprudence that the need for new thinking about the issue is now even more manifest. One problem may be nomenclature. As demonstrated later in the text, the term "description requirement" is a misnomer.
Kevin S. Rhoades, *The Section 112 "Description Requirement" – A Misbegotten Provision Confirmed*, 74 J. Pat. & Trademark Soc'y 869, 869-70 (1992)	[T]here is in fact no justification for carving out a separate "description" requirement from the "enablement" requirement in Section 112, first paragraph, that the specification contain an enabling disclosure of how to make and use the invention. In brief, the language and history of the statute support no such separate requirement, which fulfills no function or purpose not already served by the traditional enabling disclosure standard.

Neutrally Commenting on *Eli Lilly* Written Description

Citation	Quotation
Robert Greene Sterne et al., *The Written Description Requirement*, 37 Akron L. Rev. 231, 241 (2004)	It is clear that the written description requirement applies to all technologies covered by patent applications and is not limited to the unpredictable or "complex" arts. The impact of this principle is that the cost and difficulty of drafting patent applications in any art has risen significantly in recent years to adequately protect all variations and permutations of the invention.
Sean A. Passino et al., *Written Description Traps For Antibody Claims*, 86 J. Pat. & Trademark Off. Soc'y 317, 318-19 (2004)	To avoid a § 112, first paragraph rejection under the holding of *Noelle*, an applicant for a U.S. patent may want to disclose a fully characterized antigen if the applicant wants written description support for a claim to an antibody defined by its binding affinity to the antigen. Broader antibody coverage may be obtained by demonstrating the claimed antibody's ability to recognize isoforms of the antigen from one or more different species or by mapping the epitope recognized by the antibody. Furthermore, *Noelle* has implications wider than § 112, first paragraph rejections. The doctrine may be used against

	the USPTO, infringers alleging invalidity, and parties of a contested case. Under 35 U.S.C. § 102, a patent or printed publication will not anticipate a claim unless it "describes" the claimed invention. If the courts take the position that a patent or printed publication fails to describe an embodiment for the purposes of § 112, first paragraph, then it is difficult to believe that the same patent or printed publication describes the same embodiment for the purposes of § 102. . . . Clearly, this area of the law is evolving.
Robert M. Schulman, *A Review of Significant 2003 Federal Circuit Decisions Affecting Chemical, Pharmaceutical, and Biotech Inventions*, 16 No. 3 J. Proprietary Rts. 1, 1 (2004)	In the written description area, 2003 represented the first year in which the court signaled a reversal of the trend it established in 1997, requiring provision of specific sequences for applicants claiming biological molecules. The Federal Circuit is not quite ready to reverse its "written-description-plus" requirement for biotech inventions.
Lewis R. Clayton, *Inadequate Descriptions*, 4/5/04 Nat'l L.J. 12, col. 1, 12, col. 1+ (2004)	Though the Rochester inventors made, as the district court noted, "significant discoveries in this field," they did not take the "last critical step" of isolating the necessary compound, or "developing a process through which one skilled in

	the art would be directly led" to it. Absent a reversal en banc, those efforts will not be compensated under the patent laws.
Chandra Garry, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 18 Berkeley Tech. L.J. 195, 208 (2003)	The Federal Circuit in *Enzo* decided for the first time that the written description requirement may be satisfied by a biological deposit. At first glance, it appears that *Enzo* lowers the written description standard applied by the court in *Lilly*, as deposit seems an easy way to satisfy the written description requirement. Any such lowering of the written description standard, however, is by and large illusory. The decision in *Enzo* will likely be strictly limited to its facts. If not limited to its facts, the court's redefined written description is not sufficiently explained by the court so as to provide an easily workable standard for future decisions.
Jeffery M. Duncan et al., *Practitioners Be Wary: The Dangers of Functional Descriptions in Biotech Inventions*, 15 No. 10 Andrews Ent. Indus. Litig. Rep. 21 (2003)	In the last six years, several patents to biotech inventions that were otherwise valid have been struck down because the description of the invention, often by functional terms, was found wanting. One difficulty for biotech patent practitioners is that there are no bright line rules prescribing what is

	or is not an adequate written description. Instead, as the U.S. Court of Appeals for the Federal Circuit has repeatedly stated, the satisfaction of the written description requirement is a fact-specific inquiry, decided on a case-by-case basis.
After Determining That a Seller of a Egg Processing Machine May Have Induced Infringement of Patent Claiming a Method Directed High-Speed Egg Processing, the Federal Circuit Address the Written Description Requirement and the Lilly Case Again, 13 Fed. Circuit B.J. 179, 182 (2003)	This case [*Moba*] highlights the state of flux at the Federal Circuit concerning the written description requirement.
Andrea G. Reister, *Enablement & Written Description: Friend or Foe in Litigation?*, 766 PLI/Pat 383, 405-6, 409 (2003)	*Enzo/Gen-Probe* exemplifies the difficulty in annunciating the Federal Circuit's standard for written description, and the dispute within the court over the purpose of the written description requirement and how it relates to the enablement requirement. * * * It remains to be seen whether the *Lilly/Enzo/Gen-Probe* requirements for written description will survive, and supplant the cases that have dealt with written description in the context of disputes relating to priority.

Janet E. Reed et al., *Written Description: A Looser Requirement? The Federal Circuit Has Been Edging Away from the Heightened Standard That It Set Out in the 1997 "Lilly' Case*, 6/16/03 Nat'l L.J. S1, col. 1, S1, col. 1+ (2003)	In its most recent treatments of the first paragraph of 35 U.S.C. 112, the U.S. Court of Appeals for the Federal Circuit has edged away from the heightened written description requirement for biotechnology patents articulated in *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). This process has revealed dissenting opinions among the Federal Circuit judges, which may only be resolved by en banc review of the written description requirement as a whole. As a result, the standard for satisfying the written description requirement remains elusive, leaving practitioners struggling to determine the level of written description that will be deemed "adequate" to support biotechnology patent claims. * * * Though en banc review of the written description requirement seems timely, the disparate perspectives of the Federal Circuit judges make the outcome difficult to predict. It is uncertain whether a major overhaul of statutory interpretation is in the works, or whether the current interpretation will

	remain substantially intact. The patent bar and the biotechnology industry will no doubt eagerly await resolution of the current ambiguity, accompanied, it is to be hoped, by pronouncement of a clear standard for written description to be applied by the PTO during patent prosecution and by the courts in patent litigation.
Mary S. Consalvi, *The Enablement and Written Description Requirements*, 766 PLI/Pat 349, 377, 381 (2003)	With this decision [*Enzo Biochem*] and the decision in *Amgen Inc. v. Hoeschst Marion Roussel*, 314 F.3d 1313 (Fed. Cir. 2003), it is clear that written description is still in a state of uncertainty and ambiguity. * * * The law of enablement and written description under 35 U.S.C. § 112, first paragraph is constantly evolving and emerging. At the present time, there is still a lot of uncertainty in the area.
Anne Y. Brody, Ph.D., *Rochester v. Searle: Complying with the Written Description and Enablement Requirements in Early-Stage Drug Discovery*, 22 Biotechnology L. Rep. 472, 474 (2003)	This case touches on many uncharted areas of biotechnology patent law. With the emerging fields of genomics and proteomics, the law has to keep up with biotechnological advances. In the University of Rochester's pending appeal to the CAFC, the real issue for the written description

	requirement may depend on where in the time line of research and development a discovery turns into an invention. Is such a method of treatment claim valid only when a selected group of compounds is identified? Or are the solutions (e.g., the drug compounds and their screening methods) obvious once the source of the problem is determined? The determinative factor in the enablement requirement may be contingent on the definition of "undue experimentation" in the field of drug development. The amount of guidance and what is undue experimentation change as technologies progress to standardize many laboratory techniques. For example, in recent years, high-throughput screening technologies have reduced time and effort scientists expend to conduct numerous parallel experiments simultaneously. Selecting a starting material and creating a pool of its variants for screening are now conventional procedures among the researchers in biotechnology.

Todd M. Oberdick, *Section 112, Paragraph-6 – Means Claim and Limitation to Specific Algorithm – Is This a Stricter Standard Than Gentry Gallery and Related Mechanical Cases?*, 22 Pace L. Rev. 385, 390 (2002)	In light of *Gentry Gallery* and *Johnson World·vide*, a patent practitioner may be tempted to omit a precise description of a preferred embodiment of the invention for fear of making "crystal clear" that a narrow claim interpretation was intended.
Lisa A. Karczewski, Comment: *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 McGeorge L. Rev. 1043, 1086 (2000)	The Federal Circuit's trilogy of landmark biotech decisions in the past decade have made an obvious mark with respect to the future of obtaining patent protection for genetically engineered products and the specificity required for satisfying the written description requirement. Having incorporated the reasoning from these decisions into the methodology of its guidelines, only time will tell whether the USPTO's efforts will impede the patent application process for the biotechnology industry.
Scott A. Chambers, *"Written Description" and Patent Examination Under the US Patent and Trademark Office Guidelines*, IP Litigator 9, 9 (Sept./Oct.2000)	While some practitioners and the Patent and Trademark Office (PTO) cannot ignore the law as interpreted by the Court of Appeals for the Federal Circuit and must respond in a manner that continues to protect the intellectual property interests of their clients. Moreover, the Federal Circuit's clarification of the written

	description requirement suggests that some broadly drawn patents may be vulnerable to attack for lack of written description.
Cindy I. Liu, *Gentry Gallery, Inc. v. Berkline Corp.*, 14 Berkeley Tech. L.J. 123, 123 (1999)	In *Gentry Gallery, Inc. v. Berkline Corp.*, the Federal Circuit narrowed the scope of patents through the written description requirement of section 112 by announcing an omitted element test.
Laurence H. Pretty, *The Recline and Fall of Mechanical Genus Claim Scope Under "Written Description" in the Sofa Case*, 80 J. Pat. & Trademark Off. Soc'y 469, 479-80 (1998)	It remains to be seen whether *Gentry Gallery* will become a more influential precedent than *Utter v. Hiraga* in permitting attack upon a genus claim in the predictable arts by limiting patent protection to the species disclosed. . . . It may also be advisable to include a claim of extreme breadth as the first filed original claim even at the risk of presenting a claim that is highly likely to be rejected, in order to negate any inference that "written description" will bar any broader claim later.

LINN, *Circuit Judge*, with whom RADER and GAJARSA, *Circuit Judges*, join, dissenting from the court's decision not to hear the case en banc.

The panel opinion in this case perpetuates the confusion our precedent in *Lilly* and *Enzo* has engendered in establishing "written description" as a separate requirement of 35 U.S.C. § 112, paragraph 1, on which a patent may be held invalid. That precedent should be overturned. Accordingly, I respectfully dissent from the court's decision not to hear this case en banc.

Section 112 of Title 35 of the United States Code requires a written description of the invention, but the measure of the sufficiency of that written description in meeting the conditions of patentability in paragraph 1 of that statute depends solely on whether it enables any person skilled in the art to which the invention pertains to make and use the claimed invention and sets forth the best mode of carrying out the invention. The question presented by 35 U.S.C. § 112, paragraph 1, is not, "Does the written description disclose what the invention is?" The question is, "Does the written description describe the invention recited in the claims – themselves part of the specification – in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?" That is the mandate of the statute and is all our precedent demanded prior to *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

Reading into paragraph 1 of section 112 an independent written description requirement, divorced from enablement, sets up an inevitable clash between the claims and the written description as the focus of the scope of coverage. This is ill-advised. Surely there is no principle more firmly established in patent law than the primacy of the claims in establishing the bounds of the right to exclude. *See, e.g., Aro Mfg. Co. v. Convertible Top*

Replacement Co., 365 U.S. 336, 339 (1961) ("[T]he claims made in the patent are the sole measure of the grant."); *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891) ("'The rights of the plaintiff depend upon the claim in his patent, according to its proper construction.'" (quoting *Masury v. Anderson*, 16 F. Cas. 1087, 1088 (C.C.S.D.N.Y. 1873))); *White v. Dunbar*, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms."); *Burns v. Meyer*, 100 U.S. 671, 672 (1879) ("[T]he terms of the claim in letters-patent . . . define[] what the office, after a full examination of previous inventions and the state of the art, determines the applicant is entitled to."); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) ("This distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely what it is that is patented."); *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc) ("Consistent with its scope definition and notice functions, the claim requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the patentee's right to exclude."); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) ("Specifications teach. Claims claim."). The statute itself makes clear that Congress intended the claims to define the scope of coverage. 35 U.S.C. § 112, ¶ 2 (2000) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.").

The primary role of the written description is to support the claims, assuring that persons skilled in the art can make and use the claimed invention. *Id.* ¶ 1 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."); *see also Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421 (Fed. Cir. 1987) ("The purpose of the [written] description requirement . . . is to state what is needed to fulfil the enablement criteria."); *cf. In re Barker*, 559 F.2d 588, 594 (CCPA 1977) (Markey, C.J., dissenting) ("The attempt to create historical and current statutory support for a 'separate description' requirement, which was solely a judicial (and unnecessary) response to chemical cases in which appellants were arguing that those skilled in the art 'might' make and use a claimed invention, is mistaken.").

Construing section 112 to contain a separate written description requirement beyond enablement and best mode creates confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude. Under the panel's analysis, a court looks to the written description to determine the parameters of the patentee's invention – under guidelines yet to be articulated – and then determines if the claims, as properly construed, exceed those parameters. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 922-23 (Fed. Cir. 2004) ("While it is true that this court and its predecessor have repeatedly held that claimed subject matter 'need not be described in haec verba' in the specification to satisfy the written description requirement, it is also true

that the requirement must still be met in some way so as to 'describe the claimed invention so that one skilled in the art can recognize what is claimed.'" (citations omitted)). There is simply no reason to interpret section 112 to require applicants for patent to set forth the metes and bounds of the claimed invention in two separate places in the application. That is the exclusive function of the claims.

The burden of *Lilly* and *Enzo* has fallen on the biotech industry disproportionately, but, as this decision makes clear, the new-found written description requirement will affect all fields of emerging technology. *Univ. of Rochester,* 358 F.3d at 925 (rejecting a limitation of the *Lilly* written description doctrine to genetic inventions on the ground that "the statute applies to all types of inventions"). When patent attorneys set out to write patent applications, they do so for an educated audience – those skilled in the art – and attempt to describe the invention in a way that enables those of ordinary skill to make and use the invention as claimed. Before the decision in *Lilly,* the practicing bar had accepted and found workable the notion elucidated in our precedent that § 112 requires a written description sufficient to enable one of ordinary skill in the art to make and use the claimed invention – i.e., enablement. *Lilly* changed the landscape and set in motion the debate the panel opinion in this case perpetuates.

As I commented in my dissent from the court's decision not to hear the *Enzo* case en banc, "Some have praised *Lilly* for maintaining the integrity of patent disclosures and for curbing patent filings for inventions that have not yet been made but are just nascent ideas. Others have been sharply critical of *Lilly.*" *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 323 F.3d 956, 989 (Fed. Cir. 2002) (Linn, J., dissenting). That

debate continues to leave uncertain how inventions are protected, how the United States Patent and Trademark Office discharges its responsibilities, and how business is conducted in emerging fields of law. These uncertainties will remain unless resolved by this court en banc or by the Supreme Court. The issue is important, is ripe for consideration, and deserves to be clarified, one way or the other. For these reasons, I respectfully dissent from the court's refusal to consider this case en banc.

DYK, *Circuit Judge*, concurring in the court's decision not to hear the case *en banc*.

In my view the question of whether 35 U.S.C. § 112 contains a written description requirement (separate from the enablement requirement) does not merit *en banc* review. For the reasons set forth in the panel opinion and in Judge Lourie's opinion concurring in the denial of *en banc* review, I think it is clear that the statute contains such a requirement – applicable both in the context of priority and validity disputes. In this particular case the failure to satisfy that requirement was not even a close case. The appellant simply did not invent, much less describe, what was claimed.

My vote to deny *en banc* review, however, should not be taken as an endorsement of our existing written description jurisprudence. In my view we have yet to articulate satisfactory standards that can be applied to all technologies. Future panel opinions may provide the necessary clarity. If not, there may be a time when *en banc* consideration of the proper written description standards will be appropriate. But this is neither the right time, nor the right case, in which to consider those difficult questions.

Supreme Court, U.S.
FILED
OCT 28 2004
OFFICE OF THE CLERK

No. 04-476

IN THE

Supreme Court of the United States

UNIVERSITY OF ROCHESTER,

Petitioner,

v.

G.D. SEARLE & CO., INC., MONSANTO CO., PHARMACIA CORPORATION, AND PFIZER INC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION

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October 28, 2004

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QUESTION PRESENTED

Whether 35 U.S.C. § 112, which provides that a patent specification must provide a written description of both "the invention" and "the manner and process of making and using it," requires that the specification describe the invention as well as how one skilled in the art can make and use it.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondents G.D. Searle & Co., Inc. (now G.D. Searle LLC), Monsanto Company (now Pharmacia Corporation), Pharmacia Corporation, and Pfizer Inc. (collectively, "Pfizer") state that, pursuant to a transaction on April 16, 2003, Pfizer Inc. directly or indirectly owns all of the stock of Pharmacia Corporation and G.D. Searle LLC. Pfizer Inc. has no parent and no publicly held company owns 10% or more of Pfizer Inc.'s stock.

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RESPONDENTS' BRIEF IN OPPOSITION

This case involves a patent that purports to claim a method of selectively inhibiting an enzyme, but that does not disclose any means of doing so. Rather, as both the district court, Pet. App. 32a-33a, and court of appeals, Pet. App. 29a, found, the patent instructs the practitioner to find, by trial and error, a compound that selectively inhibits the enzyme in question, and to administer such an unspecified compound to a person in need of treatment. Indeed, as the courts below found, Pet. App. 19a-20a, 46a, 54a, the putative "inventors" do not claim to have known of any compound that performed the claimed function at the time of the patent's filing, or even whether such a compound then existed. Accordingly, the district court held, Pet. App. 55a-56a, 67a-68a, that the patent in question is invalid, both because it does not provide "a written description of the invention" and because it does not "enable" one skilled in the art to make and use it; and the court below affirmed, stating both that the patent lacked the "written description of the invention" required by 35 U.S.C. § 112 and that the patent quite arguably "failed to satisfy the requirements of section 102(f)" that it claim subject matter actually invented by the patentee. Pet. App. 28a, 29a-30a n.10.

Notwithstanding these multiple alternative grounds for decision and the clear invalidity of the patent in issue, the petition asks this Court to use this case as a vehicle for deciding whether 35 U.S.C. § 112 contains a "written description" requirement that is independent of the statute's so-called "enablement" requirement. The petition does so even though the district court found that the patent in issue does not enable the claimed invention, and even though the judges who voted for rehearing en banc below agreed that the question presented is a purely academic one, since they agreed that this patent does not enable, and since they recognized that the question presented has never arisen in an actual case where enablement exists. Indeed, those judges argued that, far from being an important and recurring issue

of federal patent law warranting this Court's review, the entire issue is legally "superfluous" and unlikely to arise in real litigation in a context that could affect the outcome of a case. Pet. App. 88a-89a.

Such a hypothetical and speculative issue is plainly not worthy of this Court's review. There is no alleged conflict with this Court's precedents and no conflict in judgments of the Federal Circuit — let alone any inter-circuit division of authority — but rather only persistent dissents by a few individual judges of the Federal Circuit from an unbroken line of cases recognizing and applying the independent written description requirement. As noted, however, even these judges have conceded that the application of this independent written description requirement has never made, and is unlikely to make, a difference in the outcome of any case; and the United States Patent and Trademark Office ("PTO") has in fact issued guidelines, after notice and comment, that expressly endorse the Federal Circuit's precedents on this question, and reject the position urged in the petition. Finally, as noted above, this case presents a particularly inappropriate vehicle for deciding the question presented, because the decisions below, as well as the three primary dissenters from the denial of rehearing en banc, recognized independent grounds for the judgment below regardless of how the independent written description issue would be decided. Pet. App. 23a, 29a-30a n.10, 88a.

In any event, the decision below is plainly correct. The plain language of section 112 expressly requires that a patent specification disclose a written description "of the invention" as well as a description of how to make and use that invention. The PTO has so read and administered the statute. And none of petitioner's extratextual policy arguments against applying the statute according to its terms and the PTO's construction of it have any merit. There is thus no warrant for this Court's review.

STATEMENT OF THE CASE

1. The human body produces certain enzymes called cyclooxygenases. These enzymes contribute to pain and inflammation at the sites of injuries. Non-steroidal anti-inflammatory drugs like aspirin operate by inhibiting cyclooxygenases, thereby relieving the pain and inflammation that they can cause.

Scientists have discovered that there are two different types of cyclooxygenases in the human body, only one of which is primarily associated with contributing to pain and inflammation at injury sites. COX-2 is believed to be primarily responsible for the pain and inflammation previously known to be associated with cyclooxygenases generally; the other cyclooxygenase, COX-1, occurs in the gastrointestinal tract, where it assists in the protection of the stomach lining. Aspirin and other traditional non-steroidal anti-inflammatory drugs inhibit cyclooxygenases generally, without distinguishing between COX-1 and COX-2.

In the 1990s, scientists employed by petitioner the University of Rochester (the "University") developed a method for screening non-steroidal anti-inflammatory drugs to determine their relative impact on the COX-1 and COX-2 enzymes. They applied for, and received, a patent for these methods in 1998. That patent is not at issue in this case.

In 2000, the University's scientists also obtained, a separate patent, U.S. Patent No. 6,048,850, that purports to disclose a method of selectively inhibiting COX-2. Each claim in the '850 patent involves a method of "administering a non-steroidal compound that selectively inhibits the [COX-2] gene product." Federal Circuit Joint Appendix ("JA") A0147(71:35-72:57). The patent does not, however, disclose any such compound, nor how to make such a compound. Rather, the '850 patent merely discloses a screening method to determine whether a compound acts selectively on COX-2.

Specifically, the '850 patent discloses "cells that express [COX-1] or [COX-2] exclusively," an "assay" to determine the activity of the COX-1 and COX-2 genes, and an *in vitro* assay "to evaluate" the ability "of a compound to selectively inhibit [COX-2]" using these cell lines. JA A0113(3:46-47, 56-57), A0123(24:51-58, 60-62). In other words, the patent contains no "suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention," and no guarantee that the screening method described in the '850 patent will "inherently produce" any such compound. Pet. App. 46a, 54a n.7.

2. On the same day that the '850 patent issued, the University sued respondents for allegedly infringing it. The University's lawsuit alleged that certain COX-2-specific inhibitors sold by respondents, Celebrex® and Bextra®, infringed the '850 patent. Respondents moved for summary judgment on the ground that the '850 patent was invalid for failing to meet the requirements imposed by 35 U.S.C. § 112, the provision of the Patent Law which provides:

> The specification [of a patent] shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In response, the University did not argue that the '850 patent actually disclosed any COX-2 inhibitors. Rather, the University submitted expert declarations describing general biomedical research methodologies used to identify new pharmaceutical compounds. None of the declarations stated that it was routine to create or find a COX-2-specific inhibitor of the sort alluded to in the patent. Instead, they asserted that it is routine for research-based pharmaceutical

companies to do research to try to invent new drugs, that "it would not have been uncommon . . . to undertake a drug discovery program," JA A1273 ¶ 26, that the patent "provides tools . . . for identifying non-steroidal compounds suitable for use in the claimed methods," JA A0343-44 ¶ 6, A0388 ¶ 13, that skilled artisans "would have been confident" that they could make cells needed to perform petitioner's screening assay, JA A1312-13 ¶ 43, and that skilled artisans could have performed a "rapid and routine assessment of test compounds as potential selective Cox-2 inhibitors." JA A1272 ¶ 24.

The district court granted summary judgment for respondents based on both the written description and enablement requirements of 35 U.S.C. § 112. The district court found that the '850 patent merely discloses "a wish or plan or first step for obtaining a desired result" rather than a patentable invention, and that "[t]he reader [of the patent] also learns that the patentee had not proceeded to do what was necessary to accomplish the desired end." Pet. App. 32a. The district court observed that "such an 'invention' is not really one at all." Pet. App. 32a.

The district court explained that the patent failed the written description requirement because it lacks "any suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention." Pet. App. 46a. At best, the court found, the University's patent "simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work." Pet. App. 44a.

Turning to the enablement requirement, the district court found that the patent did not disclose "any suitable compound" to use in the claimed method, and did not "explain how one can discover such a compound," Pet. App. 64a, apart from "undue experimentation, with no assurance of success," Pet. App. 60a. While petitioner's experts stated that researchers could search for a suitable compound using

"'routine' methods," the court found that the patent "provides precious little guidance" for "selecting" or "narrowing the range of candidates." Pet. App. 62a. "Tellingly, . . . what plaintiff's experts[] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds — which, as the patent makes clear, are necessary to practice the claimed method — would be suitable, nor would one know how to find such a compound except through trial and error, which hardly suggests conception of a complete invention." Pet. App. 54a. The district court concluded that petitioner's expert declarations did not support enablement because they addressed "use and function of the screening assay, rather than . . . actually discovering a suitable compound." Pet. App. 65a n.12. Thus, "[a]t most, [the patent's] description will enable a person of ordinary skill in the art to *attempt to discover* how to practice the claimed invention." Pet. App. 67a.

3. A panel of the Federal Circuit affirmed. The panel reaffirmed that, under the text of section 112 and a long line of Federal Circuit precedents, there exists a requirement that a patent specification contain a written description of the invention, and that while this requirement is related to the enablement requirement, the two are distinct. Pet. App. 9a-20a.

The Federal Circuit panel observed that "[t]he 'written description' requirement serves a teaching function, as a *quid pro quo* in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" Pet. App. 12a. The panel concluded that the '850 patent fails that requirement because it "does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods — an essential element of every claim of that patent — and has not provided evidence that any such

compounds were otherwise within the knowledge of a person of ordinary skill in the art." Pet. App. 28a.

In addition, while concluding that it need not separately reach the enablement issue in light of its ruling on the written description requirement, Pet. App. 28a, the panel expressly held that "[t]he claimed methods . . . cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art." Pet. App. 23a. Moreover, the panel also observed (Pet. App. 30a n.10) that "[h]ere the patentee has done no more than invent a search method," and, accordingly, concluded that "it might appear that the patentee also failed to satisfy the requirements of section 102(f)," which precludes the issuance of a patent where the applicant "did not himself invent the subject matter sought to be patented."

4. By a 7-5 vote, the Federal Circuit denied rehearing en banc. Pet. App. 70a, 78a n.1. Several judges wrote separately. Only three of the dissenters expressed disagreement with the merits of the panel decision, and one dissenting judge wrote to express agreement with the panel.

Judge Lourie wrote an opinion concurring in the denial of an en banc hearing, Pet. App. 74a-78a, emphasizing that "there is and always has been a separate written description requirement in the patent law." Pet. App. 74a; *see also* Pet. App. 75a ("It has always been there."). Judge Lourie explained that, to the extent that the decisions directly addressing this issue are not as numerous, this stemmed from the fact that "[l]egal holdings arise when they do because litigants raise them and courts have to decide them," and some issues related to the written description requirement simply have not arisen until recently. Pet. App. 75a.

Judge Dyk also concurred in the denial of rehearing en banc. Pet. App. 122a. While Judge Dyk recognized the need for further development of "our existing written description jurisprudence," he found that "the question of whether 35

U.S.C § 112 contains a written description requirement (separate from the enablement requirement)" "is clear." *Id.* Judge Dyk also found that this case did not present a proper vehicle for further developing the Federal Circuit's written description jurisprudence, because "[i]n this particular case the failure to satisfy that requirement was not even a close case. The appellant simply did not invent, much less describe, what was claimed." Pet. App. 122a.

Judge Newman dissented from the denial of an en banc hearing. Pet. App. 71a-73a. While Judge Newman "fully share[d] Judge Lourie's understanding of the law" on the merits, and agreed that the panel's decision rested upon "well-established and heretofore unchallenged" precedents, she expressed concern about a disagreement within the Federal Circuit regarding aspects of the court's written description requirement. Pet. App. 71a. In particular, Judge Newman expressed concern about issues raised in the context of "[t]he new biology," including the question of whether "deposit [of a biological material] in a public depository" satisfies the written description requirement. Pet. App. 71a-72a. (This case, of course, does not involve any such deposit.)

Judge Rader wrote an opinion dissenting from the denial of en banc review, which was joined by Judges Gajarsa and Linn. Pet. App. 78a-92a. Judge Rader disagreed that section 112 contains a written description requirement independent of the enablement requirement. Moreover, Judge Rader expressed the view that the written description requirement applied by the panel is "superfluous" because it "rarely, if ever, happens" that "a patent can enable an invention that is not described by the specification." Pet. App. 88a; *see also* Pet. App. 90a (stating that "as a practical matter" this situation "never occurs"). He stated that "[n]o actual case presents th[at] hypothetical," and expressly concluded that this case is no exception, because the claimed invention "was not enabled" by the '850 patent. Pet. App. 88a. Judge Linn

also wrote a dissenting opinion joined by Judges Rader and Gajarsa, arguing that section 112 should not be read "to contain a separate written description requirement beyond enablement." Pet. App. 120a.

REASONS FOR DENYING THE PETITION

The petition for a writ of certiorari should be denied. There is no conflict alleged between the decision below on the question presented and any decision of this Court, any other court of appeals, or, for that matter, any other decision of the Federal Circuit. Moreover, while the petition emphasizes that several judges of the Federal Circuit have voiced their disagreement with the overwhelming majority of that court about whether 35 U.S.C. § 112 contains an independent written description requirement, even those dissenting judges acknowledged that there is no case in which an invention has been enabled but not properly described under Federal Circuit law. Accordingly, by their own argument, the issue of concern to the dissenting judges is entirely hypothetical and, accordingly, clearly not one that warrants the time and attention of this Court. Indeed, because both the district court and the dissenting judges here found that the '850 patent did not enable any invention, and because the panel found that this patent appeared also to fail the requirements of 35 U.S.C. § 102, this case would be a particularly poor vehicle for addressing the question presented. And, in all events, the decision below is correct on the merits, as recognized by an overwhelming majority of the Federal Circuit judges, and as confirmed by published guidelines of the United States Patent and Trademark Office. There is thus no warrant whatsoever for the petition.

I. THERE IS NO CONFLICT OR UNCERTAINTY IN JUDICIAL OR ADMINISTRATIVE JUDGMENT ABOUT WHETHER A WRITTEN DESCRIPTION REQUIREMENT DISTINCT FROM THE ENABLEMENT REQUIREMENT EXISTS.

The University's primary argument is that this Court should grant certiorari to resolve an alleged "deep schism" within the Federal Circuit regarding whether section 112 imposes a "written description" requirement that is distinct from the enablement requirement. Pet. 15. In fact, no division in judicial judgment exists that would warrant this Court's review.

1. The University does not even suggest that review is justified based upon any conflict with precedents of this Court. This Court has in fact indicated its agreement with the Federal Circuit on the question presented. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 724 (2002) (noting that section 112 requires that the "application must describe, enable, and set forth the best mode of carrying out the invention"); *see also Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 433-34 (1822) (distinguishing enablement and description objects of the specification under analogous provision of predecessor statute).

Nor does the petition claim that review is warranted to resolve a conflict between the circuits. Although petitioner argues that "there can be no inter-circuit conflicts on this question," Pet. 12, the regional circuits can in fact decide substantive issues of patent law — such as the question presented in the petition — where, for example, they are raised in counterclaims. *See Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 834 (2002). But no other circuit has yet disagreed with the Federal Circuit about whether 35 U.S.C. § 112 imposes a written description requirement distinct from its enablement requirement.

Finally, petitioner does not show any genuine intra-circuit division of authority on the question raised in the petition. Despite its hyperbole about an alleged intractable division within the Federal Circuit on the question whether there is a written description requirement separate from the enablement requirement, there are no decisions of that court that are in conflict, or even in tension, with the holding in this case. On the contrary, petitioner acknowledges an unbroken line of cases spanning over thirty years uniformly affirming the existence of an independent written description requirement. Pet. 14. Indeed, as Judge Lourie explained, Pet. App. 9a-16a, the Federal Circuit, and before its creation, the Court of Customs and Patent Appeals, have consistently applied separate written description and enablement requirements for decades. *See, e.g.*, *Regents of Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64 (Fed. Cir. 1991); *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984); *In re Barker*, 559, F.2d 588, 593 (CCPA 1977); *In re Smith*, 481 F.2d 910, 914 (CCPA 1973); *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971); *In re Ruschig*, 379 F.2d 990, 995-96 (CCPA 1967).

2. In arguing that there is a "deep schism" in judicial opinion on the question presented, the University in fact relies solely on quotations from several separate opinions of individual judges on the Federal Circuit. Pet. 14-17. Those opinions include three by Judge Rader, the author of the principal dissent from denial of rehearing en banc below, *see* Pet. App. 78a-92a; *Moba, B.V. v. Diamond Automation*, 325 F.3d 1306, 1324 (Fed. Cir.) (Rader, J., concurring), *cert. denied*, 124 S. Ct. 464 (2003); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 977-78 (Fed. Cir. 2002) (Rader, J., dissenting), and two from other judges, one of whom did *not* join in dissenting from rehearing en banc below, *see Moba, B.V.*, 325 F.3d at 1327-28 (Bryson, J., concurring); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1361

(Fed. Cir. 2003) (Clevenger, J., dissenting). The petition thus presents no conflict in judgments of the Federal Circuit (let alone a true *inter*-circuit conflict), or even in dictum in opinions for that court, but rather relies solely on the persistently expressed, separate views of a small minority of judges on the Federal Circuit. This Court, of course, does not sit to review such minor debates arising in the natural and orderly course of the conduct of judicial business.

Indeed, this Court's intervention would be particularly inappropriate here. Judge Rader, the principal judge expressing those dissenting views in the Federal Circuit, has argued that the question presented is a purely academic one. According to Judge Rader, the resolution of this question has never affected the outcome of any case, including this one. On Judge Rader's view, the written description requirement imposed by the Federal Circuit is "superfluous" because "[n]o actual case" has involved or likely will involve a specification that satisfies the enablement requirement but fails the written description requirement. Pet. App. 88a. Judge Rader expressly included this case, noting that the University's invention "was not enabled." Pet. App. 88a. Not only has "no case ever presented" the question in the petition in a context where it could affect the outcome, but Judge Rader saw it as "unfathomable" that such a case could arise. Pet. App. 89a.

In other words, while Judges Rader, Gajarsa and Linn (the latter two of whom joined Judge Rader's discussion) disagree with the distinct written description requirement long-established by the Federal Circuit, even they have argued that their disagreement is a theoretical one with no practical significance to the outcome of any real cases. Thus, far from being an important or recurring issue warranting this Court's attention, the question of federal law discussed by the dissenters and presented by the petition is entirely academic and speculative and may never arise in a real case in a way that could affect the outcome. This

Court's precious time and resources are not properly wasted on such a question.

3. The University also suggests that the Federal Circuit jurisprudence recognizing an independent written description requirement is in conflict with the views of the Executive Branch. Pet. 19. It is not. In fact, the University ignores that the PTO has issued authoritative guidelines on this issue — after publication of proposed guidelines in the Federal Register and extensive public comment — that expressly endorse the view of the Federal Circuit.

In 2001, the PTO issued *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099 (Jan. 5, 2001). The Guidelines endorse a written description requirement "separate and distinct from the enablement requirement" that can be satisfied only by "describ[ing] the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *Id.* at 1104; *see also id.* at 1100 ("Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria."). In particular, the Guidelines provide that the written description requirement is not satisfied "if the knowledge and level of skill in the art would not permit one skilled in the art to *immediately envisage* the product claimed from the disclosed process." *Id.* at 1105 (emphasis added). Moreover, the PTO expressly stated its belief that the Guidelines are "fully consistent with binding precedent of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit," and that, in contrast to the University's position here, "the USPTO does not find . . . *Eli Lilly* to be in conflict with binding precedent." *Id.* at 1100.

Contrary to the suggestion in the petition (Pet. 19), the *amicus* brief of the United States in *Enzo Biochem* does not contradict the PTO's Guidelines or the decision below. The government's *Enzo Biochem* brief expressly endorses both

the PTO's Guidelines and the Federal Circuit's written description requirement. *See* Brief of *amicus curiae* United States in *Enzo Biochem*, No. 01-1230, at 4, 8-9 (Fed. Cir. July 2, 2002). Indeed, the brief explicitly states that "[e]ven if a written description provides the 'manner and process of making and using' the invention, a description of the invention itself is still necessary to enable others to make and use it." *Id.* at 5. This brief thus provides no support for certiorari on the question presented here.

It is true, of course, that in *Enzo Biochem*, the government did seek en banc clarification — not of the existence of the independent written description requirement at issue here — of the precise contours of the written description requirement as applied to patents that refer to "the placement of biological matter in public depositories," *id.* at 2, an issue that the government believed could "put[] at risk numerous biological patents that rely on a reference to a deposit to help meet section 112," *id.* at 4. But that question is not presented by the petition here. Moreover, the panel decision to which the government was responding, 285 F.3d 1013 (Fed. Cir. 2002), was subsequently vacated, and the subsequent panel decision, 323 F.3d 956 (Fed. Cir. 2002), expressly adopted the PTO's position regarding biological deposits and endorsed the written description guidelines. *See id.* at 964. Indeed, the irrelevance of the issues discussed in the government's *Enzo Biochem* brief to this case is confirmed by the fact that Judge Dyk dissented from the first panel decision in that case, *see* 285 F.3d at 1024-28 (Dyk, J., dissenting), yet expressly agreed with the rule of decision and outcome in this case, noting that "[i]n this particular case the failure to satisfy [the written description requirement] was not even a close case." Pet. App. 122a.

4. For similar reasons, the petition also errs in its reliance (Pet. 10, 16) on some Federal Circuit judges' concern about a related but separate issue — namely, what is necessary to satisfy the independent written description requirement in

various contexts. Specifically, just as Judge Dyk and the United States noted uncertainty in *Enzo Biochem* over the precise contours of the written description requirement in the factual context of patents referring to deposited biological materials (but did so without questioning the *existence* of such a requirement separate from enablement, Pet. App. 122a), several other judges have expressed a desire to clarify the scope of the written description requirement in other contexts. *See, e.g.*, *Housey Pharms., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1357 (Fed. Cir. 2004) (Newman, J., dissenting); *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 1002-05 (Fed. Cir. 2000) (Lourie, J., dissenting); *SunTiger v. Scientific Research Funding Group*, 189 F.3d 1327, 1337-38 (Fed. Cir. 1999) (Lourie, J., dissenting). The opinion of Judge Newman below is another such example: While having no doubt that the question presented in the petition was correctly decided by the panel (since the written description requirement is "well-established and heretofore unchallenged"), Pet. App. 71a, Judge Newman nonetheless noted that "[t]he new biology has indeed raised new and important questions, with implications for policy as well as law." Pet. App. 72a. Judge Dyk shared this concern, and wrote separately to emphasize that the Federal Circuit had "yet to articulate satisfactory standards that can be applied to all technologies." Pet. App. 122a. But, as Judge Dyk nonetheless concluded, this case did not present the appropriate vehicle to resolve such questions, because "[i]n this particular case the failure to satisfy [the written description requirement] was not even a close case. The appellant simply did not invent, much less describe, what was claimed." Pet. App. 122a. For the same reason, this Court could not effectively use this case to address such issues; indeed, the question presented by the petition is limited to *whether* an independent written description requirement exists and does not cover *what* the proper contours of such a requirement are. Thus, the petition's

references to these other, distinct issues are just obfuscating rather than illuminating.

II. PRUDENTIAL CONCERNS COUNSEL AGAINST USING THIS PETITION TO RESOLVE THE QUESTION PRESENTED.

Not only does the petition fail to present an important question of federal law about which courts are in conflict, it also presents a poor vehicle for deciding the question that it does present. Prudential concerns thus also counsel against granting this petition.

1. A case ordinarily presents a poor vehicle to use for resolving a question presented when there are alternative grounds for the decision below that would produce the same result "in any event." *The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 183 (1959). "While this Court decides questions of public importance, it decides them in the context of meaningful litigation." *Id.* at 184; *see also, e.g.*, *Springfield v. Kibbe*, 480 U.S. 257 (1987) (per curiam) (dismissing certiorari where issue did not concretely affect case); *Rescue Army v. Municipal Court*, 331 U.S. 549, 575 (1947) (declining review of question presented "in highly abstract form"). Thus, the existence of separate grounds for the same result no matter which way the question presented is decided in this Court supports a decision to "await a day when the issue is posed less abstractly." *The Monrosa*, 359 U.S. at 184. A case is also a poor vehicle for deciding a question if the issue is not squarely presented under its facts. *See, e.g.*, *Belcher v. Stengel*, 429 U.S. 118, 119 (1976) (per curiam) (dismissing certiorari because "the question framed in the petition for certiorari is not in fact presented by the record now before us"). This vehicle limitation is particularly crucial in the context of a purely "hypothetical" issue that is unlikely to arise in *other* cases. *Ticor Title Ins. Co. v. Brown*, 511 U.S. 117, 122 (1994) (per curiam).

2. This case presents a poor vehicle for resolution of the question presented for all of the foregoing reasons.

First, the outcome of the case does not depend upon the resolution of the question presented, because there are at least two alternative grounds for invalidating the '850 patent recognized below. The district court also invalidated the patent on the independent ground that it was not enabled, a requirement that petitioner repeatedly acknowledges properly exists under section 112. *E.g.*, Pet. 2, 13, 19. The Federal Circuit also expressly found the factual predicate for an enablement invalidation (although it did not need formally to reach that issue in light of its ruling on the written description requirement, Pet. App. 28a), finding that "[t]he claimed methods thus cannot be practiced based on the patent's specification, even considering the knowledge of one skilled in the art." Pet. App. 23a. The panel showed that the patent did not even allow one skilled in the art to know what the invention was, much less how to make it. Pet. App. 23a-24a. Equally tellingly, even the judges who dissented from the denial of rehearing agreed that the alleged invention "was not enabled" by this patent. Pet. App. 88a.

Similarly, the panel decision indicated that there was yet another independent ground for the judgment. Section 102(f) precludes the issuance of a patent where the applicant "did not himself invent the subject matter sought to be patented." Because "[h]ere the patentee has done no more than invent a search method," the panel here observed that "it might appear that the patentee also failed to satisfy the requirements of section 102(f)." Pet. App. 30a n.10. Such an additional alternative ground for decision underscores that the petition is not the right vehicle for this Court to use to address the independent written description requirement question.

Second, the petition does not squarely present the question on facts that might illuminate its proper resolution. A proper vehicle would be one where there are findings *both* that the

written description is not satisfied *and* that the enablement requirement *is* satisfied; such a vehicle would provide the context suitable to decide the effect of the written description requirement separate from enablement. In contrast, in a case (such as this one) where there is no specific finding that the patent in question meets the enablement standard (and, indeed, the district court and the judges below have indicated that it does not), the case provides no means to disentangle the two distinct yet overlapping requirements. The issue described in the petition is thus not squarely "presented by the record" in this case in the fashion that this Court has indicated is prudentially wise and necessary for certiorari review. *Belcher*, 429 U.S. at 119.

III. THE FEDERAL CIRCUIT CORRECTLY HELD THAT SECTION 112 REQUIRES A WRITTEN DESCRIPTION OF THE INVENTION BEYOND MERELY SATISFYING THE ENABLEMENT REQUIREMENT.

In all events, the panel's decision is correct on the merits. The petition errs in suggesting otherwise.

1. Contrary to the petition, the plain language of the statute supports, rather than undermines, the Federal Circuit's judgment that section 112 requires a written description of the invention beyond merely satisfying the enablement requirement. Section 112 provides that "[t]he specification shall contain a written description" of two separate things: First, it must "contain a written description of the invention." Second, it must describe "the manner and process of making and using it." These two requirements are connected by the word "and," thus expressly mandating that *both* requirements must be satisfied. *See, e.g.*, *In re Barker*, 559 F.2d 588, 591 (CCPA 1977) (noting that a contrary reading would "render superfluous the requirement that the specification contain a written description — 'of the manner and process of making and using it [the invention],'" for "if there were a description enabling 'any person skilled in the

art . . . to make and use,' there would be no need to require a description of the 'manner and process of making and using'").

The University has no response to this basic textual point. Instead, its only textual argument is that the enablement requirement that follows the latter of these two requirements modifies both of them rather than merely the "making and using" description requirement, thus providing that both the description of the invention and the description of how to make and use it must only satisfy the enablement requirement. Pet. 18-19. This argument is in error.

In the first place, the enablement requirement directly follows the "making and using" description requirement and by its terms refers to the specificity needed in allowing a skilled artisan "to make and use" the invention. It thus relates to the language only of the second description requirement, not the requirement that the invention be described.

Even more fundamentally, the University's argument is entirely irrelevant. Even if the University were correct that both the descriptions "of the invention" *and* "of the manner and process of making and using it" are grammatically connected to the enablement requirement, that would in no way relieve the applicant of the statutory obligation to give "a written description of the invention" as well as how to make it. The enablement requirement is a further specification on what must be contained in the referenced description; it is not a repudiation of the need for a written description that actually identifies the invention being patented. Petitioner offers no reading under which it could obviate the need to satisfy the required description "of the invention" distinct from how to "make and use" it. Indeed, petitioner's construction improperly renders much of the statutory language superfluous and redundant. *See Barker*, 559 F.2d at 592 (noting that "it is presumed that Congress did not use superfluous words").

2. Petitioner similarly errs in suggesting that an independent written description requirement serves no purpose. Pet. 20-22. Among other things, that requirement has the function of "distinguish[ing the invention] from all other things before known." Patent Act of 1793 § 3, 1 Stat. 318, 321; *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 434 (1822) (noting need to prevent the inventor from "pretending that his invention is more than what it really is"). While the University argues that this function has somehow been abrogated because those words do not themselves occur in the current version of the Patent Act, Pet. 19-20, the requirement that the specification describe the invention itself, separate from the manner of making and using it, remained in the statute. And that requirement continues to serve the function of "ensur[ing] that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000); *see also, e.g.*, *In re Wright*, 866 F.2d 422, 424 (Fed. Cir. 1989) ("The specification as originally filed must convey clearly to those skilled in the art the information that the applicant has *invented* the specific subject matter later claimed." (internal quotation marks omitted; emphasis added)).

As the Federal Circuit has indicated, the written description requirement also "serves a teaching function, as a '*quid pro quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" Pet. App. 12a (quoting *Enzo Biochem*, 323 F.3d at 970). The PTO has similarly stated that the written description requirement serves both to convey the information that the patentee has invented the claimed subject matter and to further public knowledge of the invention in exchange for exclusivity. *See* 66 Fed. Reg. at 1104.

3. Without a citation to the decision below, the petition also erroneously asserts that "the panel dispensed with the statutorily-required perspective of persons skilled in the art." Pet. 22. The panel did no such thing. In fact, it noted that the written description requirement must "be met in some way so as to describe the claimed invention so that one skilled in the art can recognize what is claimed." Pet. App. 14a (internal quotation marks omitted). Moreover, the panel repeatedly applied the perspective of one skilled in the art as the relevant benchmark in its discussion of the issue. *See, e.g.*, Pet. App. 19a, 23a, 28a, 29a.

4. The University's argument that the decision below disrupts settled expectations, Pet. 24-26, is equally unfounded. That argument rests upon the false premise that the panel applied "a new patentability doctrine." Pet. 24.

In fact, as shown above, the plain language of section 112, an unbroken line of Federal Circuit precedents, and the guidelines published in the Federal Register by the PTO have all put inventors and others on notice of the independent written description requirement. As Judge Newman emphasized below, settled expectations are fully in line with the panel's decision: "It has always been necessary to disclose and describe what is patented. It has never been the law that one can claim what is not made known and set forth in the patent." Pet. App. 72a. Judge Lourie made this point similarly emphatically, noting that "there is and always has been a separate written description requirement in the patent law." Pet. App. 74a; *see also* Pet. App. 75a (noting that "the interpretation of the statute as containing a separate written description requirement did not originate with *Lilly*. It has always been there." (citations omitted)).

Indeed, it is the University's position that would upset settled expectations and reliance interests. The University itself acknowledges that the doctrine they criticize has been binding law for more than three decades, and both the University and Judge Rader agree that it took on increased

vitality seven years ago in the *Eli Lilly* case. Pet. 14; Pet. App. 78a-79a. Indeed, the PTO published guidelines on the issue to ensure widespread and common understanding of the requirement. It is thus the University's request that this Court overturn over thirty years of precedent and the applicable administrative guidelines that would drastically upset settled expectations and reliance interests.

5. Finally, contrary to the petition, the written description requirement does not deprive research institutions of patent protection for their inventions or undermine the Bayh-Dole Act. Pet. 26-29. The University mischaracterizes the decision below in stating that it "preclude[s] patenting inventions founded on basic research." Pet. 27. So long as there is an actual invention that can be and is described in the specification, the decision below does nothing to prevent an invention's patentability. And, without such an invention, free-floating "basic research" has never been patentable. *See, e.g.*, *Brenner v. Manson*, 383 U.S. 519, 536 (1966) ("[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

The Bayh-Dole Act is even more clearly irrelevant. As the panel noted, Pet. App. 27a, nothing in that statute has anything to do with the requirements for patentability; rather, that statute governs relationships among the government, universities, and small businesses in the use of inventions stemming from federally funded research. 35 U.S.C. §§ 200-12.

In fact, the substantive provisions of the Bayh-Dole Act govern the ownership and licensing of "inventions," which is expressly defined to mean "any invention or discovery *which is or may be patentable* or otherwise protectable under this title." *Id.* § 201(d) (emphasis added). Thus, the covered "inventions" are expressly limited to those that meet the independent requirements for patentability, including those requirements imposed by section 112.

CONCLUSION

The petition for a writ of certiorari should be denied.

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October 28, 2004

(3)

No. 04-476

SUPREME COURT, U.S.
FILED
NOV 8 - 2004
OFFICE OF THE CLERK

In The Supreme Court of the United States

UNIVERSITY OF ROCHESTER,

Petitioner,

v.

G.D. SEARLE & CO., INC., MONSANTO CO., PHARMACIA CORPORATION, AND PFIZER, INC.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

REPLY BRIEF FOR PETITIONER

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November 8, 2004

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REPLY BRIEF FOR PETITIONER

A. The Instant Case Is An Ideal Vehicle For Resolution Of The Extremely Important Question Presented

Respondents are wrong that this case involves a "hypothetical" or "purely academic" issue. Br. in Opp. 1-2, 12, 16 (citations omitted). There is nothing academic or hypothetical about the Federal Circuit's invalidation of petitioner's patent for failure to meet that court's judicially-fashioned separate written description requirement. That is the sole ground on which the court of appeals ruled.

1. There are not "multiple alternative grounds" for the decision below, as respondents claim. *See* Br. in Opp. 1, 2, 16-18. The Federal Circuit did not hold that the patent failed to meet the enablement requirement. Indeed, it expressly declined to address that issue. Pet. App. 28a ("In view of our affirmance of the district court's decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further.").

Moreover, respondents ignore the fact that this case comes to the Court from a grant of summary judgment. In addition to relying on the patent's statutory presumption of validity under 35 U.S.C. § 282, petitioner submitted expert evidence that its patent does indeed enable one skilled in the art to make and use the invention. (1) Professor Schofield averred that those skilled in the art "would have been able to practice the inventions of the '850 patent with respect to the discovery of therapeutically useful COX 2 selective inhibitors on the basis of the disclosures of the . . . application together with their skill in the art" and "could have practiced the inventions . . . without undue experimentation." Fed. Cir. J. App. A1208. (2) Professor McGiff directly addressed respondents' objection that there was no specific compound identified, explaining that "it would not be necessary for one of ordinary skill in the art to know the structure of a compound before screening it to determine whether it was suitable for use in the claimed method." *Id.* at A344. (3) Indeed, Dr. Suto averred, without contradiction, that "a

major reason why [respondents'] selective Cox-2 inhibitor program succeeded so quickly [in making a compound] was because of the detailed knowledge available about the Cox-2 target (which information was set out in the [petitioner's] September 1992 [patent] application)." *Id.* at A1278.

Respondents did not introduce *any* contrary evidence of what one skilled in the art could or could not make or use based on the patent. Because the enablement standard requires the perspective of one skilled in the art, petitioner's unrefuted evidence, especially considered in light of the burden on respondents to overcome the statutory presumption of validity by clear and convincing evidence, *see* Pet. 22-23, means that whether the patent meets the enablement standard (which it does) is a question that cannot be resolved adversely to petitioner on summary judgment. Pet. C.A. Br. 29-35. The trial court's ruling to the contrary was error that the Federal Circuit did not reach because it based its decision on the failure to meet its separate written description requirement. *See* Pet. App. 28a.

The passing comment in the course of a discussion of a "hypothetical policy analysis" by one of the dissents from denial of rehearing *en banc*, to the effect that petitioner's invention was not enabled, cannot substitute for evidence in the record of the opinion of one skilled in the art, as respondents would have it. Br. in Opp. 9, 12, 17. And the panel's citation to the skilled-in-the-art requirement (Br. in Opp. 21) likewise does not alter the fact that the record contains no evidence that those skilled in the art could not make and use the invention based on the patent. Although the panel may have suggested that it was applying the perspective of one skilled in the art, it could not have applied such a perspective that was contrary to the uncontroverted skilled-in-the-art evidence of record and the presumed validity of the patent.

2. Petitioner's patent did not fail to satisfy the requirements of 35 U.S.C. § 102(f). Respondents' reference (Br. in Opp. 1, 9, 17) to dicta in a final footnote of the opinion below suggests that Section 102(f) prevents patents for inventions such as petitioner's that constitute

methods or processes. But Section 102(f) provides only that an applicant is not entitled to a patent if the applicant "did not himself invent the subject matter sought to be patented," thereby simply ensuring that an applicant does not seek to patent the invention of another inventor. 35 U.S.C. § 102(f); *see OddzOn Prods. v. Just Toys, Inc.*, 122 F.3d 1396, 1401 (Fed. Cir. 1997).

The Patent Act addresses the issue of what constitutes a patentable invention not in Section 102(f) but in Section 101, which authorizes an individual who "invents or discovers any new and useful process, [including an art or method,] machine, manufacture, or composition of matter," including "a new use of a known process, machine, manufacture, composition of matter, or material" to obtain a patent. 35 U.S.C. §§ 101, 100(b) (defining "process"). Plainly, petitioner's discovery of Cox-2 and its invention of a new method of treating pain (described by respondents' chief medicinal chemist as the "holy grail in this area," Fed. Cir. J. App. A760) fall squarely within the Act's scope under Section 101.

In any event, respondents never raised an argument regarding Section 102(f) in either the district court or the Federal Circuit, suggesting that they, too, recognized the paucity of the argument. Because the issue was not raised or passed on below, respondents should not now be allowed to invoke it to prevent review of the wide-reaching and erroneous ruling below.

3. a. Respondents suggest (Br. in Opp. 9, 12-13) that there is little practical significance to whether there is a written description requirement untethered to enablement. They cite one of the dissents from denial of rehearing *en banc* for the proposition that "the application of this independent written description requirement has never made, and is unlikely to make, a difference in the outcome of any case." Br. in Opp. 2; *id.* at 1, 9, 12. That is a strange argument – that for 30 years, and amidst great controversy, the Federal Circuit has been engaged in a meaningless exercise of attempting to create a separate written description requirement, and a pointless internal debate about whether there is any statutory support for such a

requirement, because whatever the result, it does not make any difference. In fact, the reality is to the contrary.

In the nearly contemporaneous opinion in *Chiron Corp. v. Genentech, Inc.*, a panel of the Federal Circuit, including some of the dissenters below, held that the patent application in that case met the enablement requirement of Section 112, but did not meet the Federal Circuit's separate written description requirement. *See* 363 F.3d 1247 (Fed. Cir. 2004), *petition for cert. pending*, No. 04-477. *See also In re Curtis*, 354 F.3d 1347, 1357 (Fed. Cir. 2004) (affirming PTO determination that patent application did not contain sufficient written description even though it enabled persons skilled in the art to make and use invention).

The United States Patent and Trademark Office (PTO) itself has expressly recognized that "situations will arise" involving the Federal Circuit's separate written description requirement and the enablement requirement where "one requirement is met but the other is not. Federal Circuit case law demonstrates many circumstances where enablement or written description issues, but not both, were before the Court." *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement*, 66 Fed. Reg. 1099, 1101 (2001).

Indeed, by holding that its separate written description requirement invalidates petitioner's patent for failure to identify an implementing compound, Pet. App. 23a-24a, the Federal Circuit vividly demonstrates the impact of its additional requirement. By divorcing written description from enablement – and requiring a specific formula for a compound – the Federal Circuit has imposed a requirement that is not viewed through the lens of one skilled in the art, even where it is clear from the evidence introduced by petitioner that identification of an exact chemical formula was *not* required for persons skilled in the art to make and use petitioner's invention. This is dramatic, and not an inconsequential point as respondents attempt to make it.

b. Respondents also argue (Br. in Opp. 17-18) that because the separate written description and enablement requirements are two "distinct yet overlapping requirements,"

the court of appeals' failure to find that the enablement requirement was met means that the separate written description requirement is somehow not squarely presented in this case. But that, of course, begs the very question presented by this case. Under the correct interpretation of the statute there are not two distinct requirements; rather, the written description required is a description required "as to enable" and not for some separate judge-made purpose.

Respondents' view that it would be suitable for the Court to decide the question presented in a case only where the written description requirement is not satisfied but the enablement requirement is satisfied (Br. in Opp. 17-18), is inconsistent with notions of proper court decisionmaking whereby a court does not decide an issue that it does not have to. After all, if a court finds that a party loses on one ground (separate written description), a further holding that it would prevail on a second ground (enablement) is unnecessary to the judgment, and hence equivalent to dicta. The Federal Circuit ruled against petitioner on the ground that the patent failed to comply with the court's separate written description requirement, recognizing that, in so doing, it did not need to reach enablement. It would create perverse incentives if this judicial restraint became a reason not to grant *certiorari*.

B. Review Is Necessary To Eliminate The Disagreement In The Federal Circuit And The Resultant Uncertainty So As To Establish A Clear Rule To Govern The Application And Administrative Issuance Of Patents

1. Respondents attempt to bolster their argument that there is no disagreement or uncertainty on the question presented by claiming (Br. in Opp. 2, 9, 13-14, 20, 22) that the PTO "expressly endorse[s]" the Federal Circuit's interpretation of Section 112 to impose a separate written description apart from enablement. But the PTO has done no such thing.

First, the PTO's Guidelines, which respondents claim "confirm[]" the correctness of the decision below (Br. in

Opp. 9), were promulgated in furtherance of the PTO's duty to follow the law, including Federal Circuit precedent, *not* as an expression of the PTO's independent view that the Federal Circuit's interpretation of Section 112 is correct. *See* 66 Fed. Reg. at 1100 ("the USPTO is bound by the Federal Circuit's decision in *Eli Lilly*"); *see also* 64 Fed. Reg. 71,427, 71,429 (1999) ("The [PTO] does not intend to impose a written description requirement that is more robust than that set forth by the courts.").

Second, respondents mischaracterize (Br. in Opp. 13-14) the United States' *amicus* brief on behalf of the PTO in support of rehearing *en banc* in *Enzo BioChem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002). The United States flatly asserted that "[a] straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention." Brief of *Amicus Curiae* United States in *Enzo BioChem*, No. 01-1230 at 5 (filed July 2002), *available at* http://www.uspto.gov/web/offices/com/sol/ambriefs/Enzo.pdf (U.S. *Enzo BioChem amicus* brief); *id.* at 9 (same). It noted that the Federal Circuit had not adopted that straightforward reading and had "not rel[ied] on the text of the statute." *Ibid*; *see also id.* at 5-9 (discussing "at least three different possible Federal Circuit tests for an adequate 'written description'" in the course of urging *en banc* review to provide much needed guidance).

2. Respondents also claim that this Court has "indicated its agreement with the Federal Circuit on the question presented," quoting dicta in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), and citing an interpretation in *Evans v. Eaton*, 20 U.S. (7 Wheat) 356 (1822), of the Patent Act of 1793. Br. in Opp. 10. But *Festo*, in stating that an "application must describe, enable, and set forth the best mode," says nothing about the *relationship* between description and enablement, and thus cannot be read as expressing an opinion on the issue raised by this case. And the text of the 1793 Act specified a different role for the description, that was later eliminated by Congress and no longer exists in the current statute. *See* Pet. 20 (discussing interpretation

of Patent Act of 1793 in *Evans v. Eaton* and 1836 amendment).

3. a. Respondents' argument that *certiorari* should be denied because "there are no decisions" of the Federal Circuit "that are in conflict, or even in tension, with the holding in this case" is belied by the extensive discussion of such cases both by the dissenting judges below and the vast array of academic commentators who have analyzed the chaotic status of the Federal Circuit panel opinions on the issue. There is not an "unbroken line of cases spanning over thirty years uniformly affirming the existence of an independent written description requirement," as respondents claim. Br. in Opp. 11. The petition makes abundantly clear that the Federal Circuit's cases since 1967 are anything but uniform or consistent and have failed to provide adequate notice to patent applicants and examiners as to the source or meaning of a separate written description requirement untethered to the enablement standard of the statute. *See* Pet. 15-17.

Indeed, in the year prior to the instant case, two panel opinions affirmatively indicated that the separate written description standard of *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998) (itself a dramatic departure from precedent that had not previously relied on the separate written description requirement to invalidate patents) did not extend to cases such as the instant one. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) (suggesting that the more demanding written description requirement of *Eli Lilly* was limited to "new or unknown biological materials"); *Moba v. Diamond Automation*, 325 F.3d 1306, 1320 (Fed. Cir.) ("In more recent cases . . . this court has distinguished *Lilly*."), *cert. denied*, 124 S. Ct. 464 (2003).

b. The inconsistent panel opinions of the Federal Circuit are as close as one will come to conflicting rulings because panels of the Federal Circuit are bound by prior three-judge panel decisions regardless of whether they agree with that panel's decision, unless the earlier panel is

reversed *en banc*. *See* Fed. Cir. R. 35(a)(2); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564 (Fed. Cir. 1991).

This Court has reviewed numerous decisions of the Federal Circuit when a substantial number of its judges have raised significant questions about a legal rule adopted by the majority. *See, e.g., Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995) (reviewing Federal Circuit opinion in which suggestion for rehearing *en banc* was denied by a vote of six to five); *Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83 (1993) (reviewing Federal Circuit opinion in which suggestions for rehearing *en banc* were denied over the dissents of three judges). The five dissenting votes from denial of rehearing *en banc* in this case should therefore weigh in favor of review. This is particularly so when one of the judges (Judge Newman) believes that Section 112 contains a separate written description requirement but nonetheless urged *en banc* review to quell the "continuing debate in panel opinions applying divergent law," Pet. App. 71a; and another (Judge Bryson) had joined the panel in *Eli Lilly*, supporting a separate written description requirement, but subsequently expressed doubts about whether the separate written description requirement is "based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1." Pet. App. 78a n.1; *Moba*, 325 F.3d at 1328 (Bryson, J., concurring).

4. Respondents' implication that the Court should deny review because "no other circuit has yet disagreed with the Federal Circuit" on its separate written description requirement ignores reality. As respondents note (Br. in Opp. 10), the other Circuit Courts of Appeals do retain limited appellate jurisdiction over cases that may involve patent law issues that are raised, for example, in counterclaims. But the number of appeals involving patent law heard by Circuits other than the Federal Circuit is so small as to be inconsequential. *See* Andrew G. Heinz, *Note: Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 84 B.U. L. Rev. 1103, 1130 n.224 (Oct. 2004) (since 2002, "over four hundred patent law cases have been heard by the Federal Circuit, while less than ten have been diverted to other jurisdictions"). Thus, no ruling by another Circuit on the question presented here (let alone a

ruling disagreeing with the Federal Circuit's interpretation to which other courts tend to defer on patent matters), is likely to ever occur, even though the Federal Circuit's ruling is contrary to the plain language of the statute.

C. The Federal Circuit's Interpretation Defies The Clear Statutory Text And Is Contrary To This Court's Plain Meaning Precedent

As the United States has previously declared, a "straightforward reading of the text of section 112" does not support the Federal Circuit's creation of a separate written description under Section 112 that is distinct from enablement. U.S. *Enzo BioChem Amicus* Br. 5. The petition demonstrates that the Federal Circuit's statutory interpretation is contrary to this Court's precedent instructing courts not to "read into the patent laws limitations and conditions which the legislature has not expressed." Pet. 18 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)).

Respondents contend that Section 112 requires a written description of two things – "of the invention" and "of the manner and process of making and using it." Br. in Opp. 18. Respondents ignore the statutorily required purpose of the written description of those two things, which must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." 35 U.S.C. § 112.

Respondents and the Federal Circuit disregard the grammar and syntax of Section 112 and read the statute as if the words "as to enable any person skilled in the art to which it pertains . . . to make and use the same" do not refer to the written description of the invention. But those words must refer to the written description of the invention because the final word "same" is a reference back to the earlier word "invention." The manner in which the commas are used in Section 112 further confirms this reading.

The problem is that the panels of the Federal Circuit have created a *separate* written description requirement distinct from the statutory requirement for a written

description that is in such terms as to enable. The Federal Circuit demands a written description that does more than enable. The judicially-created separate requirement has shifted over time. In this case, it was interpreted to require identification of a precise chemical compound, not just the method for treatment and the mechanism to identify a compound. By doing so, it went far beyond the enablement standard, which relies on what one skilled in the art can make and use based on the patent and which was supported by the uncontroverted expert evidence in the record. *See* Pet. App. 23a-24a. The ruling below jeopardizes all patents on methods by applying requirements found nowhere in the statutory text and should not be allowed to stand.

CONCLUSION

For the reasons set forth above and in the petition for a writ of *certiorari*, the petition should be granted.

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NOVEMBER 8, 2004

(2)

Supreme Court, U.S.
FILED
NOV 8 - 2004
OFFICE OF THE CLERK

No. 04-476

IN THE

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Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICI CURIAE THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE UNIVERSITY OF TEXAS SYSTEM, CARNEGIE MELLON UNIVERSITY, CASE WESTERN RESERVE UNIVERSITY, CORNELL UNIVERSITY, WISCONSIN ALUMNI RESEARCH FOUNDATION, THE RESEARCH FOUNDATION FOR SUNY, THE UNIVERSITY OF MARYLAND, EMORY UNIVERSITY, THE UNIVERSITY OF FLORIDA, THE JOHNS HOPKINS UNIVERSITY IN SUPPORT OF THE PETITION

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THE INTEREST OF THE AMICI CURIAE[1]

The *Amici Curiae* are a group of eleven public and private universities and private educational research corporations whose research scientists conduct fundamental and ground-breaking research. The *Amici* are: The Regents of the University of California, three campuses of the University of Texas System (The University of Texas M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center at Dallas, The University of Texas Medical Branch at Galveston) Carnegie Mellon University, Case Western Reserve University, Cornell University, Emory University, the University of Florida, The Johns Hopkins University[2], The Research Foundation for the State University of New York, the Wisconsin Alumni Research Foundation (WARF), and the Attorney General of the State of Maryland on behalf of the State and the University of Maryland, Baltimore.

The *Amici* have a substantial interest in the Petition for a Writ of Certiorari filed by the University of Rochester. The *Amici* write specifically to emphasize the detrimental impact of the Federal Circuit's recent written description

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1. No counsel for any party authored this brief either in whole or in part, and no persons other than the *Amici Curiae* and their counsel made any monetary contribution to its preparation or submission. The parties' written consents to the filing of this brief have been filed with the Clerk of the Court.

2. The Johns Hopkins University joins as an *Amicus* for the limited purpose of requesting resolution of the issue of whether there is a separate written description requirement. The University does not join a position on whether a separate written description requirement is required by the statute but does believe that all statutory requirements were met by the Rochester patent.

precedent[3] on the ability of research institutions to protect their inventions and to transfer this technology to the private sector for further development and commercialization. The application of the heightened written description requirement to inventions created by research institutions is of immense concern to the *Amici* and has far-reaching implications for the patentability of ground-breaking research conducted at universities. Under this new written description doctrine, if the inventor has not actually reduced to practice and provided a detailed description of the structure of the claimed invention, the claims may be invalidated for insufficient written description. This Court's decision whether to consider this issue will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector.

SUMMARY OF ARGUMENT

This case provides the Court with an opportunity to bring clarity and certainty to the nature and scope of the disclosure requirement embodied in 35 U.S.C. § 112, Paragraph 1 ("§ 112, P. 1"). The *Amici* seek the Court's attention on this issue for three reasons. First, this case squarely presents the issue of statutory interpretation of the disclosure provision of § 112, P. 1. Second, this case crystallizes the intense intra-circuit conflict on the proper interpretation of the written description requirement, which the Federal Circuit repeatedly has refused to resolve by *en banc* review. Third, and foremost to the *Amici*, this case disrupts the settled expectations of the inventing community, particularly of universities engaged in basic research. The fate of pioneering inventions based on such fundamental research depends on the correct statutory

3. The Federal Circuit's recent written description precedent includes *Regents of the University of California v. Eli Lilly, Inc.*, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, and most recently, *University of Rochester v. G.D. Searle.*

interpretation of § 112, P. 1. If the statutory interpretation set forth in *University of Rochester v. G.D. Searle*, 358 F.3d 916, 921, *reh'g denied*, 375 F.3d 1303 (Fed. Cir. 2004) prevails, these inventions will be exceedingly difficult to patent and previously issued patents on such important inventions may be invalidated.

At issue in this case is the statutory construction of § 112, P. 1, one of the most important statutes in patent law. Because the statute embodies the *quid pro quo* of the constitutional patent bargain, the statute must be interpreted in a manner such that the patent bargain is properly effectuated. The plain language of the statute mandates one disclosure provision that requires a written description of the invention in such "full, clear, concise, and exact terms" to enable the skilled artisan to make and use the claimed invention. Furthermore, when the statute is viewed in its proper historical and legal context, this interpretation of the statute is confirmed. Neither the express statutory language nor a contextual analysis supports the separate, free-standing written description requirement set forth by the Federal Circuit in *Rochester*.

The new statutory interpretation of § 112, P. 1 fundamentally changes patent law in a manner that disrupts the expectations of the inventing community. By instituting a rule under which inventions must be described in a precise structural way, it creates a higher bar to patentability and a powerful weapon to invalidate already issued patents. Such a rigid rule conflicts with the goals of providing a uniform body of patent law and encouraging innovation. This interpretation also frustrates the important federal policy of encouraging the commercialization of federally-supported non-profit entity originated technology as premised in the Bayh-Dole Act and undermines the innovative partnership between government, universities and private industry.

The Federal Circuit is deeply divided on the issue of whether the statute requires a separate written description

beyond that sufficient to enable a skilled artisan to make and use the invention. Yet the court repeatedly refuses to clarify its confusing written description jurisprudence. Since the *Lilly* decision in 1997, the written description issue has percolated through various panels of the Federal Circuit. These divergent opinions cry out for a "better informed and more enduring pronouncement by this Court." *Arizona v. Evans*, 514 U.S. 1, 24 n.1 (1995). The issue is ripe for review and deserves clarification.

UNDER A PROPER CONSTRUCTION OF 35 U.S.C. § 112, P. 1, WRITTEN DESCRIPTION OF THE INVENTION MUST BE SUFFICIENT TO ENABLE

A. Section 112, Paragraph 1 Must Be Interpreted to Effectuate the Patent Bargain

Before this Court is the fundamental question of the proper statutory interpretation of the 35 U.S.C. § 112, P. 1. This question is essential to patent law because the disclosure requirement of § 112, P. 1 embodies the *quid pro quo* of the patent bargain. In return for an enabling disclosure, the patentee receives the right to exclude others from making, using or selling its invention for a limited period of time.[4]

As this Court has recognized, the patent bargain is carefully crafted to balance the benefits between the inventor and the public.

> The applicant . . . who is willing to reveal to the public the substance of his discovery and 'the best

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4. Article I, § 8, clause 8, of the Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

> mode . . . of carrying out his invention' . . . is granted 'the right to exclude others from making, using or selling the invention throughout the United States' for a certain period. The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. . . .

Bonito Boats, Inc. v. Thunder Craft Boats Inc., 489 U.S. 141, 150-51 (1989). *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) ("[T]o obtain a utility patent, a breeder must describe the plant with sufficient specificity to enable others to 'make and use' the invention after the patent term expires. The disclosure required by the Patent Act is "the *quid pro quo* of the right to exclude.").

The benefit to the public derives from the ability to use the invention after the patent expires. Accordingly, the *quid pro quo* of the patent bargain is not achieved unless the public is taught how to make and use the patented invention. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

> [T]he patent laws require inventors to describe their work in 'full, clear, concise, and exact terms,' 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.

Id. See also Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944) ("The quid pro quo is

disclosure of a process or device in sufficient detail to enable one skilled in the art to practice the invention once the period of monopoly has expired. . . .") The disclosure provision of § 112, P. 1 must be interpreted in a manner that effectuates the patent bargain.

Notably, the patent bargain does not require description for description's sake. If one of skill in the art can understand what the invention is and how to make and use it, the objectives of the patent bargain have been achieved. In the context of university research, the heightened requirement of a precise structural description impedes the prompt transfer of pioneering discoveries to the public. Researchers must divert precious resources to needlessly disclose permutations of the invention already appreciated by the skilled artisan. To require more description than necessary for enablement skews the carefully crafted balance of the patent bargain and frustrates the essential policies of encouraging innovation and competition.

B. The Proper Interpretation Based On The Express Statutory Language Is A Disclosure Sufficient to Enable

A plain reading of the statute confirms that the proper interpretation of § 112, P. 1 is a disclosure of the claimed invention sufficient to enable. Section 112, P. 1 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same. . . .

According to the express statutory language, the written description of the invention must be sufficient to enable the skilled artisan to make and use the claimed invention.

See Festo, 535 U.S. at 731 ("[T]he patent laws require inventors to describe their work in 'full, clear, concise, and exact terms. . . .'") As aptly described by Chief Judge Markey:

> There is no surplusage in saying, as the Congress in effect did, "a written description of the invention
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> * * * in such full, clear, concise, and exact terms as to enable," and "[a written description] of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable * * *." On the contrary, Congress saved words by specifying, in a single prepositional phrase, that the description of the invention, and the description of the manner of making and using it, shall both be in "such full, clear, concise, and exact terms as to enable." Section 112, first paragraph, is a simple sentence, with a comma after "it," making the phrase "in such full * * * the same" a modifier of both objects of the verb "contain." All before that comma prescribes what shall be described. The phrase following the comma prescribes how and for whom it shall be described.

In re Barker, 559 F.2d 588, 594-95 (CCPA 1977). No other disclosure is statutorily required.

C. The Written Description Requirement Never Was Interpreted As a Free-Standing Patentability Standard Prior to Lilly

The historical and legal context of the disclosure provision demonstrates that no written description of the invention beyond enablement is required by the modern statute. Prior to the introduction of claims, the Patent Statute required that the patent applicant

> deliver a written description of his invention, and of the manner of using, or process of

> compounding, the same, in such full, clear and exact terms, as to distinguish the same from all things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound and use the same. . . .

Evans v. Eaton, 20 U.S. 356, 430 (1822). This early written description requirement is the "historic predecessor of modern claiming requirements." Mueller, Janice M., *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 Berkeley Tech. L.J. 615, 620 (1998). After claims were introduced in 1870, the written description no longer served the public notice function and that part of the statute was deleted.

From 1870 to the present, the statute remained virtually unchanged. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 27 (1997). ("The 1952 Patent Act is not materially different from the 1870 Act with regard to claiming, reissue, and the role of the PTO.") According to one commentator, The written description requirement became an "historical anachronism without a role in the statutory scheme." Mueller, 13 Berkeley Tech. L.J. at 620.

In 1967, the Court of Customs and Patent Appeals ("CCPA") added a judicial gloss to the disclosure requirement of § 112, P. 1. *In re Ruschig*, 379 F.2d 990 (CCPA 1967). The court employed the judicial fiction of a separate written description rule to policy priority.[5] As Judge Rich, the first

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5. The judicially created written description requirement was used in three circumstances: 1) where an applicant asserts entitlement to an earlier filing date of a previously filed application; 2) in the interference context; and 3) in a case involving a single application, where the claim at issue is added subsequent to filing of the application. *In re Smith and Hubin*, 481 F.2d 910, 914 (CCPA 1973).

judge to use written description in this way, explained: "The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976).

In view of the express statutory language of § 112, P. 1, some judges of the CCPA questioned whether the judicially created written description rule was necessary. *See In re Barker*, 559 F.2d at 594 (Markey, C.J., dissenting). As Chief Judge Markey explained:

> The attempt to create historical and current statutory support for a 'separate description' requirement, which was solely a judicial (and unnecessary) response to chemical case in which appellants were arguing that those skilled in the art 'might' make and use a claimed invention is mistaken.
>
> * * *
>
> [I]t would have been better if the court had held, in certain past chemical cases, that whatever 'enablement' was present, it was not in 'full, clear concise and exact terms,' rather than to have created a 'separate description' gloss."

Id. at 594-95.

Early Federal Circuit precedent reflected both views of the disclosure requirement of § 112, P. 1.[6] In 1991, the Federal

6. Compare *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985), *quoting In re Kaslow*, 707 F.2d 1366, (Cont'd)

Circuit reaffirmed the separate written description requirement for policing priority found in the *Ruschig* line of cases. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). The court acknowledged that the separate requirement was a judicial creation and not a matter of statutory interpretation. *Id.* at 1561. *Vas-Cath* remained the leading case in written description precedent until the Federal Circuit's decision in *Regents of the University Of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

UNIVERSITY RESEARCH FLOURISHED BASED ON A WRITTEN DESCRIPTION SUFFICIENT TO ENABLE

In the 1980's, the expansion of patentable subject matter and new federal patent policy stimulated fundamental research at academic institutions. These changes significantly impacted the biotechnology industry and spurred the development of intellectual property rights. First, this Court opened the legal floodgates to patenting of biotechnology research when it expanded the scope of patentable subject matter to include living organisms. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

Second, Congress enacted the Bayh-Dole Act. Bayh-Dole was designed to use the patent system to encourage the transfer of technology generated by government-supported research to the public for its benefit and welfare. 35 U.S.C. § 200 ("It is the

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(Cont'd)
1375 (Fed. Cir [illegible]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'"), with *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1421 (Fed. Cir. 1987), *cert. denied*, 486 U.S. 1008 (1988) ("The purpose of the description requirement of [§ 112, P. 1] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.").

policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development. . . ."). The highly productive university-industry relationships fostered by Bayh-Dole yielded new biomedical products and spawned a robust U.S. biotechnology industry. *See* Locke, Scott D., *Patent Litigation Over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole*, 8 Va. J.L. & Tech. 3 (2003).

The Bayh-Dole Act created a federal uniform patent policy that "revitalize[d] the American economy and scientific community by removing the obstacles that the federal government had developed previously against technology transfer. . . ." Dueker, Kenneth Sutherlin, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 Food Drug L.J. 453 (1997). Central to Bayh-Dole was the role of patents in facilitating technology transfer between university labs and private industry. *See* Eisenberg, Rebecca S., *Symposium on Regulating Medical Innovation: Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1698-99 (1996). Universities needed to attract commercial licensees to invest in development because they were not equipped to develop new discoveries into commercial products. Vesting patent ownership in universities facilitated this process by providing a source of exclusive rights that would supply the incentive for the private sector to engage in such development efforts.

Bayh-Dole became the foundation of university technology transfer.[7] 52 Food & Drug L. J. at 508. Prior to

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7. *The Economist* classified the Bayh-Dole Act as "Possibly the most inspired piece of legislation to be enacted in America over the past half-century . . ." and further referred to it as "Innovation's Golden Goose." *The Economist*, 2002 WL 7248586 (December 14, 2002).

Bayh-Dole, fewer than 250 patents were issued to universities annually, and many valuable research ideas never reached the marketplace. *Id.* Ten years later, that number had risen to over 1600 patents per year, 80% of which resulted from federally funded research. *Id.* By 1996, university licensing activity was having a major economic impact, adding more than 24.8 billion dollars and 212,500 jobs to the national economy each year. Hamilton, Clovia, *University Technology Transfer and Economic Development Proposed Cooperative Development Agreements Under the Bayh-Dole Act*, 36 Marshall L. Rev. 397, 408 (2003). Against the backdrop of this highly successful implementation of federal patent policy, the drastic change in written description law occurred.

THE NEW WRITTEN DESCRIPTION DOCTRINE UPSETS THE SETTLED EXPECTATIONS OF RESEARCH INSTITUTIONS

In 1997, the Federal Circuit for the first time applied the judicially created written description requirement as a general disclosure requirement in place of the statutorily mandated enablement standard. *Lilly*, 119 F.3d at 1566-1567. Borrowing heavily from prior precedent concerning biotechnology inventions,[8] the court imposed a *per se* written description test, under which the inventor must demonstrate that its biotechnology invention has been reduced to practice and described in structural detail.

Lilly sent a shock wave through public and private research institutions. Before *Lilly*, adequate written description of chemical and biotechnological compounds had been satisfied by descriptions in terms of function, properties, methods of making, or any other manner sufficient to convey possession of the invention. Mueller, 13 Berkeley Tech. L.J.

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8. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

at 624. By requiring a precise structural description, *Lilly* "obscure[d] the function and purpose of the written description requirement by unnecessarily restricting the manner in which possession of a biotechnological invention can be conveyed." *Id.* at 633. Moreover, *Lilly* instituted a *per se* rule of written description that eliminated the perspective of one of skill in the art and required far more disclosure than necessary to satisfy the enablement requirement. Instead of focusing on the next ground-breaking discovery, *Lilly* required that university researchers describe every variant of their last invention in excruciating detail.

Following *Lilly*, the Federal Circuit in *Rochester* manufactured a separate statutory basis for its new free-standing written description requirement. By parsing the statute such that the enablement clause modifies only the second part of the written description, the panel concluded that three separate requirements are contained in the statutory provision: (1) a written description of the invention; (2) a written description of the manner and process of using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same; and (3) the best mode. *University of Rochester v. G.D. Searle*, 358 F.3d 916, 921, *reh'g denied* 375 F.3d 1303. Relying on its new statutory interpretation, the Federal Circuit in *Rochester* vastly expanded the reach of the new written description rule to all technologies.

These drastic changes in the disclosure requirement of § 112, P. 1 dramatically upset the settled expectations of the inventing community. Not only does the new written description doctrine impact the patenting of new inventions, it also threatens the validity of already-issued patents. Further, the new written description doctrine undermines the policies of Bayh-Dole, and frustrates prompt disclosure of new inventions to the public.

A. The New Written Description Requirement Frustrates Prompt Disclosure of New Inventions To The Public

The new, free-standing written description requirement frustrates the Constitutional objective of early disclosure of inventions to the public because of the added costs and burdens associated with preparing a sufficiently detailed specification.[9] Not only are inventors required to actually reduce their inventions to practice, but they also must provide a precise detailed description. In *Moba B.V. v. Diamond Automation*, Judge Rader illustrated this problem for biotechnology inventions:

> Even if a drafter of biotechnological patents now knows the new law, compliance may tax a drafter beyond reasonable limits. . . . [A] "precise definition" of the new protein, as required by *Lilly*, apparently requires tedious disclosure of thousands of potential permutations of the amino acid sequence that all fall within a proper description of the protein's functions, properties, and DNA source.

325 F.3d 1306, 1325 (Fed. Cir. 2003) (Rader, J. concurring) (footnote omitted).

The extra work may take months of researcher time, consume precious research dollars that could be used to fund other projects and delay disclosure of the fundamental invention and thus its exploitation by others. Without the speedy disclosure of biotechnology inventions, the public

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9. *See* Jeffie A. Kopczynski, *A New Era for §112? Exploring Recent Developments in the Written Description Requirement as Applied to Biotechnology Inventions*, 16 HARV. J.L. & TECH. 229, 253 (Fall 2002).

may "very well be deprived of life-saving technology, such as pharmaceutical drugs to treat a life-threatening medical disease." Kelly, David, *The Federal Circuit Transforms the Written Description Requirement into a Biotech-Specific Hurdle to Obtaining Patent Prosecution for Biotechnology Patents*, 13 ALB. L.J. SCI. & TECH. 249-250 (2002).

The new written description requirement also significantly increases the risk for venture capitalists and other investors, particularly investors in biotechnology companies. It almost certainly will reduce future funding for, and investment in, biotechnology research. Kopczynski, 16 HARV. J.L. & TECH. at 252-53. If inventors are less likely to be able to fully realize the financial benefits of their research through valid and enforceable patents, then private investors and public funds are much less likely to see a return on their investment dollars. *Id.*

B. Under the New Written Description Requirement, Issued Patents Risk Invalidity

The new written description doctrine has become a powerful weapon in the arsenal of accused infringers and places a cloud of uncertainty on the validity of already issued patents. Prior to 1997, inventors provided a disclosure that was sufficient to enable those skilled in the relevant art to make and use the claimed invention. The *Rochester* decision, however, measures each and every patent application against its precise structural written description standard. "Under this new disclosure test, every case where the written description does not specifically disclose some feature of the claimed invention will give rise to a validity challenge." *Rochester*, 375 F.3d at 1314 (Rader, J., dissenting).

This Court repeatedly has cautioned against adopting such sweeping changes to patent law. *Festo*, 535 U.S. at 739,

citing Warner-Jenkinson, 520 U.S. at 28. ("[F]undamental alterations in [patent] rules risk destroying the legitimate expectations of inventors in their property.") "To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision." *Id*, *citing Warner-Jenkinson* at 32 n.6. Especially in the university sector, a written description requirement severed from enablement can have severe consequences, depriving the public of fruits of federally-supported basic research.

C. The New Written Description Doctrine Interferes with the Policy of Bayh-Dole

The new, free-standing written description doctrine frustrates the policy objectives of Bayh-Dole. The increased burden on university researchers to describe their inventions (far beyond that required for enablement) has a chilling effect on the innovative and economic success realized under the Bayh-Dole Act. The heightened written description bar taxes the resources of many university and non-profit entities "beyond reasonable limits," *Moba*, 325 F.3d at 1325 (Rader, J. concurring), by forcing them to perform further development activities more appropriately allocated to the private sector. Rather than straining to respond to a written description requirement, the preparation for which may be costly and time consuming, research institutions instead may be forced to surrender their valuable patent rights. The heightened written description requirement thus resurrects the barriers to innovation and competition that Bayh-Dole removed.

THE DEEP CONFLICT IN THE FEDERAL CIRCUIT OVER WRITTEN DESCRIPTION MUST BE RESOLVED BY THIS COURT

The *Amici* strongly urge the Court to grant the University of Rochester's Petition in this case. Although cognizant of the deleterious effect of the new written description requirement on the biotechnology industry, the deeply divided Federal Circuit refuses to resolve this conflict. Since the *Lilly* case was decided in 1997, the issue of written description has percolated in the Federal Circuit. *See Rochester*, 375 F.3d at 1327 (Linn, J., dissenting from denial of rehearing *en banc*) ("*Lilly* changed the landscape and set in motion the debate the panel opinion in this case perpetuates.") As Judge Newman explained, "The issue of whether patent law contains a separate written description requirement has percolated through various panels of the [Federal Circuit] on a variety of facts." *Id.* at 1305 (Newman, J., dissenting). This percolation has yielded a great number of divergent opinions by the judges of the Federal Circuit.[10]

The Federal Circuit routinely issues split decisions in biotechnology patent cases that raise written description. For example, in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), the court strictly applied the *Lilly* rule and invalidated the patent for lack of written description. This opinion created "an immediate firestorm." *See Rochester*, 375 F.3d at 1308 (Rader, J., dissenting from denial of rehearing *en banc*). Within a few months, the Federal Circuit vacated its original opinion and issued a second opinion that reversed the result. *Id.*

10. *See Moba B.V. v. Diamond Automation*, 325 F.3d 1306 (Fed. Cir. 2003). In *Moba*, Judge Rader urged the overruling of the *Lilly* decision. *Id.* at 1326. Judge Bryson, who sat on the *Lilly* panel, indicated that rather than overrule *Lilly*, the proper result might be to overrule the entire *Ruschig* line of cases to eliminate entirely a separate written description requirement. *Id.* at 1328.

The Federal Circuit denied the subsequent petition for rehearing *en banc*, accompanied by four separate opinions. Two judges expressed the view that written description is preeminent: the *quid pro quo* of the patent system. *Enzo*, 323 F.3d at 971. In contrast, at least three other judges viewed written description as subsumed in the enablement inquiry. *Id.* at 981. Judge Rader stated that *Lilly* and *Enzo* apply a "new, free-standing disclosure requirement" that requires more specific disclosure than enablement, and "threatens to further disrupt the patent system by replacing enablement." *Id.* at 982. Judge Linn opined that the measure of sufficiency of the written description doctrine "should depend solely on whether it enables a person skilled in the art . . . to make and use the claimed invention." *Id.* at 988.

In *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313 (Fed. Cir. 2003), a different panel limited the *Lilly* rule to new or unknown biological material. *Id.* at 1332. Judge Clevenger dissented, stating that the district court's approach was not "faithful to this court's articulation of the written description requirements of section 112 as expressed in *Lilly*." *Id.*

In *Rochester*, the Federal Circuit fractured over written description. Five separate opinions accompanied the order denying rehearing *en banc*, with each judge advocating a different interpretation of the statute.

Two judges concurred. Judge Lourie argued for a separate written description requirement mandated by statute: "Contrary to the assertions of the appellant, certain amici, and some of the dissenters, there is and always has been a separate written description requirement in the patent law." *Rochester*, 375 F.3d at 1305. Although Judge Dyk also concurred, he commented that his concurrence "should not be taken as an endorsement of our existing written description jurisprudence." *Id.* at 1307.

Judge Newman, although professing agreement with Judge Lourie's view, dissented: "This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products. The appropriate forum is now the *en banc* tribunal, not continuing debate in panel opinions applying divergent law." *Id.* at 1304.

Judge Linn also dissented, opining that "the measure of the sufficiency of written description" depends on whether it enables a skilled artisan to make and use the claimed invention. *Id.* at 1325. He further explained:

> The question presented by 35 U.S.C. § 112, paragraph 1, is not, 'Does the written description disclose what the invention is?' The question is, 'Does the written description describe the invention recited in the claims—themselves part of the specification—in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?' That is the mandate of the statute and is all our precedent demanded prior to Regents of the University of California v. Eli Lilly & Co. . . .

Id.

Finally, Judge Rader dissented, stating that there was no legal basis for the new, free-standing written description requirement. Under both a plain reading of the statute and legal precedent, "enablement [is] the only substantive test . . . in the first paragraph of § 112." *Id.* at 1308 n.3. Judge Rader also pointed out that the new requirement "changes the established rules of claiming and disclosing inventions" and creates consequences not considered by the court or intended by Congress. *Id.* at 1313.

The Federal Circuit is deeply divided over the statutory interpretation of § 112, P. 1. If left unresolved by this Court, contradictory, panel-specific decisions concerning patentability and invalidity will continue to issue. Such continued uncertainty does great harm to the patent system and in particular, the biotechnology industry.

CONCLUSION

The continued application of the new written description requirement threatens to destroy the partnership among government, industry and universities that has fueled the biotechnology industry and produced many life-saving biomedical products. The issue of written description is a "frontier legal problem that deserves resolution." *See Arizona v. Evans*, 514 U.S. 1, 24 n.1 (1995). This Court can provide an "informed and enduring final pronouncement" on this issue. *Id.*

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